HLL BIOTECH LIMITED
(Subsidiary of HLL Lifecare Limited)
(A Government of India Enterprise)

TENDER DOCUMENT FOR

SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF LYOPHILIZERS AT INTEGRATED VACCINES COMPLEX, CHENGALPATTU

PROJECT NO: 120310

DOCUMENT NO: NPI-120310-EQP-S1-TD-06

REVISION NO.: 00

SEPTEMBER 2014

PROJECT NAME: INTEGRATED VACCINES COMPLEX

PREPARED By :NNE PHARMAPLAN INDIA Ltd.

nne pharmaplan®

APPROVED By : HLL BIOTECH LIMTED

HBL Protecting Lives

TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF LYOPHILIZERS AT INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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SECTION I
Notice Inviting Tender (NIT)
HLL Biotech Ltd.

INVITES TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF LYOPHILIZERS AT INTEGRATED VACCINES COMPLEX, CHENGALPATTU, CHENNAI

Tenders are invited from vendors for supply, installation commissioning and validation of following equipments:

Schedule. No	EQUIPMENTS	Equipment ID	Capacity / Size	QTY	EMD	Tender fee
I	Lyophilizer	F1-LYO 01	$10m^2$: 40,000 vials/batch (2R)	1	Rs. 2.87 Million	525 USD or Equivalent
		F1-LYO 02	$20m^2$: 80,000 vials / batch (4R)	1		

Note: The list may vary (increase / decrease) during order finalisation.

Details regarding important dates are as follows:

Sl No.	Description	Schedule
i.	Pre Bid Meeting Date & Time	26-09-2014at 11:00 HRS
ii.	Pre Bid Meeting Venue	**HLL Biotech Limited, TicelBiopark Campus (Module no. 013 - 015), CSIR Road, Taramani, Chennai- 600 113**
iii.	Closing date & time for receipt of Tender	17-10-2014, 16:00 Hrs
iv.	Time and date of opening of Technical Bids	17-10-2014, 16:30 Hrs
v.	Venue of Opening of Techno Commercial Tender	**HLL Biotech Limited, TicelBiopark Campus (Module no. 013 - 015), CSIR Road, Taramani, Chennai- 600 113**

Interested parties may visit www.hllbiotech.com/www.lifecarehll.com / &http://eprocure.gov.in/cppptto download the Tender. Subsequent amendments/ addendum if any will be published in these websites, The parties are advised to visit the website regularly for updates. Tenders in sealed envelopes superscribing “Tender for Supply, Installation, Commissioning and Validation of Lyophilizers at Integrated Vaccines Complex, Chengalpattu” may be submitted to the address mentioned in Serial no. v of the table above.

INSTRUCTIONS TO BIDDERS

1. The successful bidder will have to enter into a written Contract / Agreement with the Purchaser, the terms and conditions of which are enclosed herewith.

2. The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialed/stamped.

3. Bidder must be careful to deliver a bonafide tender. Any tender which proposes any alterations to any of the conditions laid down which proposes any other conditions or any description whatsoever is liable to be rejected.

4. Intimation of tenders' quotation by a telegram/fax will not be considered.

5. Tenders must be accompanied by a certified true copy of the Power of Attorney in favour of the signatory to the tender which should interalia empower him/her to bind the firm to Arbitration Clause given in the Articles of Agreement and Contract conditions.

6. In case a blank tender is being submitted, it should be marked prominently **'BLANK'** on the envelope and signed by the authorized person.

7. In view of postal and other delays, the tenders should be posted sufficiently in advance of the last date fixed for receipt of tenders or be sent by a special messenger. Tender received late shall be liable for rejection.

8. Prices shall be written in ink and shall be entered both in figures and words. In case of discrepancy the figure quoted in words shall be taken as accurate. In case of any discrepancy in the unit and amount, the unit rate shall be taken as accurate.

9. Prices quoted by the bidder shall be firm and valid even if the contract is split in two or more parts among different bidders.

GENERAL INFORMATION

PROJECT LOCATION	HLL BIOTECH LIMITED, CHENNAI INTEGRATED VACCINES COMPLEX, CHENGALPATTU
PROJECT TITLE	INTEGRATED VACCINES COMPLEX, CHENGALPATTU
CORPORATE OFFICE	**HLL Biotech Limited,** **TicelBiopark Campus (Module no. 013-015),** **CSIR Road, Taramani,** **Chennai- 600 113Ph no. 044-22544949** Email : ramanr@hllbiotech.com
PROJECT MANAGEMENT CONSULTANT	NNE Pharmaplan India Limited Noida : B-15, Sector 2 Noida – 201 301 Tel: 0120 – 4775100, Fax: 0120 – 4775200 Bangalore Office: # 12, Achiah Shetty Layout R.M.V. Extension Sadashivanagar Bangalore – 560080 Tel.: 080 - 49056300
CLIMATE	Maximum Temperature: 39.4°C Minimum Temperature: 18.3°C
ACCESS TO SITE	By Road (Chennai to Chengalpattu GST Road). Nearest Railway Station is Chengalpattu Nearest airport is Chennai

1. Introduction

HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India,) is implementing "an Integrated Vaccines Complex (IVC) - a project of national importance' at Chengalpattu, near Chennai. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India.

HLL Biotech Limited has associated with NNE Pharmaplan India Limited, hereinafter called as “NP” has been appointed as “Engineering Consultants”. NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices. This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian FDA (Schedule M), WHO/GMP regulations.

One amongst the several other jobs is to supply, install and commission the equipments / systems.

The scope of work involved is detailed in the subsequent paragraphs and is precise to the extent possible. However, it is expected from the supplier to consider and supply all those required for successful installation and functioning of the equipment / system.

2. Scope of Vendor

- The scope of vendor would be to comply to the enclosed URS, plan, supply, execute commission & validate the system as per URS and drawings.
- Quote for the unit against the URS, along with all options. The price to include all spare parts; documentation; packing; freight charges; start-up & commissioning; complete qualification package (FAT, SAT, DQ, IQ, OQ, PQ) and training and charges whatsoever required to complete the task in all respects to ensure the equipment operation is in accordance with the requirements of design documents.
- Involve with the client and the consultants to establish documented evidence that the proposed design of the system is in compliance with the GMP requirements mentioned in the User Requirement Specification, Installation requirement specification and Risk Analysis.
- The complete system should be fabricated and installed as per design review report and the regulations mentioned in the URS (Under point number 2.0) and ultimately allows to validated as per NPI Validation philosophy prepared based on Indian FDA (Schedule M), WHO/GMP regulations
- Quality and Project Planning: The Quality and Project Plan should define the activities to be performed, their timing, who will perform them, the control mechanisms to be used, and the deliverable items. Project Time Schedule must be created for that purpose. This document should define:
    - ✓ Project Milestones
    - ✓ Project Activities
    - ✓ Planned start and end date of each activity
- Quality Assurance activities during manufacturing: E.g. Collecting the material certificates, surface roughness certificates, welding documentation, etc.
- System Build (assembly and system integration): The final assembly of the mechanical, electrical, and control components (hardware and software) into an integrated functional

system should be performed by the vendor – according to the design documentation and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams).

- Construction Review: The integrated functional system is reviewed against the design documentation of the component manufacturers and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams). QC inspection and test reports
- Testing: Vendor to describe testing not related to specific user requirements, but which is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of pressure vessels. Details as follows:

  a) Pressure Vessel Testing: Prior to System Build, the pressure vessel should be subjected for pressure test in accordance with the applicable Pressure Vessel Code.
  b) Functional Testing: The Functional Testing is not related to specific user requirements, but is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of the system.
  c) Factory Acceptance Testing: The Factory Acceptance Test is a important milestone. The following tests and inspections will be performed but not limited to:

     1. Inspection to verify that all deliverables are available for shipping
     2. Inspection to verify that the correct system was built
     3. Testing to verify correct operation

  d) Note: FAT is critical to the delivery on time and equipment performance.

- Installation: Installation is a set of activities that have to be completed before site acceptance testing can start. Such activities include: putting in place, leveling, connecting media (including electrical power), turning on media and checking for leakages, fixing any leakages, checking direction of rotation for electrical motors, calibration, etc. The installation –has to be performed by the vendor
- Pre-Delivery Inspection and Final Inspection: The Final Inspection should be the last quality related activity performed before delivery to the user site and thus need to be performed after Factory Acceptance Testing.
- **Turnkey (if any): Supply, Installation, Commissioning and Validation ofLyophilizer.**
- Project Management: Activities or the procedures to be followed, and responsibilities related to Project Management are as follows:

  a) **Project communication:** Biweekly project update should be provided by the vendor in the early stage of this project. While two months before the FAT, Weekly update should be in place.
  b) **Communication paths:** In general, all communication of the vendor shall be directed through the vendor Project Manager. The vendor Project Manager should forward the information as necessary.
  c) **Means of communication:** E-mail messages and facsimiles (fax) may be used for communication as alternatives to traditional letters and telephone conversations.
  d) **Sanctity of communication:**This also applies to decisions (e.g. approvals, accepted/rejected change requests, etc.), which always shall be communicated in writing. Such e-mail messages or facsimiles are considered equally binding as signed paperdocuments provided that the following data is provided:

     - The full name of the person making the decision.

- The date of the decision

- Progress reporting: See section Project Communication for details on how the progress may be communicated to the user company
- Documentation Management: Documents need to be trustworthy, reliable, authentic, and available for as long as required by applicable legal, regulatory, or business standards.

SECTION - II
GENERAL INSTRUCTIONS TO TENDERERS (GIT)
CONTENTS

A. PREAMBLE

1. Definitions and Abbreviations:

1.1 The following definitions & abbreviations, which have been used in these documents shall have the meanings as indicated below:

1.2. Definitions:

(i) "Purchaser" means the organization and / or its representatives (consultants) purchasing goods and services as incorporated in the Tender Enquiry document. Purchaser is HBL, Chennai

(ii) "Tender" means Bids / Quotation / Tender received from a Firm / Tenderer / Bidder.

(iii) "Tenderer" means Bidder/ the Individual or Firm submitting Bids / Quotation / Tender

(iii) "Supplier" means the individual or the firm supplying the goods and services as incorporated in the contract.

(iv) "Goods" means the articles, material, commodities, livestock, furniture, fixtures, raw material, spares, instruments, machinery, equipment, medical equipment, industrial plant etc. which the supplier is required to supply to the purchaser under the contract.

(v) "Services" means services allied and incidental to the supply of goods, such as transportation, installation, commissioning, provision of technical assistance, training, after sales service, maintenance service and other such obligations of the supplier covered under the contract.

(vi) "Earnest Money Deposit" (EMD) means Bid Security/ monetary or financial guarantee to be furnished by a tenderer along with its tender.

(vii) "Contract" means the written agreement entered into between the purchaser and/or consignee and the supplier, together with all the documents mentioned therein and including all attachments, annexure etc. therein.

(viii) "Performance Security" means monetary or financial guarantee to be furnished by the successful tenderer for due performance of the contract placed on it. Performance Security is also known as Security Deposit.

(ix) "Consignee" means the organization/person to whom the goods are required to be delivered as specified in the Contract. If the goods are required to be delivered to a person as an interim consignee for the purpose of despatch to another person as provided in the Contract then that "another" person is the consignee, also known as ultimate consignee.Consignee is HBL, Chennai

(x) "Specification" means the document/standard that prescribes the requirement with which goods or service has to conform.

(xi) "Inspection" means activities such as measuring, examining, testing, gauging one or more characteristics of the product or service and comparing the same with the specified requirement to determine conformity.

(xii) "Day" means calendar day.

1.3 Abbreviations:

i. "T E Document" means Tender Enquiry Document
ii. "NIT" means Notice Inviting Tenders.
iii. "GIT" means General Instructions to Tenderers
iv. "SIT" means Special Instructions to Tenderers
v. "GCC" means General Conditions of Contract
vi. "SCC" means Special Conditions of Contract
vii. "DGS&D" means Directorate General of Supplies and Disposals
viii. "NSIC" means National Small Industries Corporation
ix. "PSU" means Public Sector Undertaking
x. "CPSU" means Central Public Sector Undertaking
xi. "LSI" means Large Scale Industry
xii. "SSI" means Small Scale Industry
xiii. "LC" means Letter of Credit
xiv. "DP" means Delivery Period
xv. "BG" means Bank Guarantee
xvi. "ED" means Excise Duty
xvii. "CD" means Custom Duty
xviii. "VAT" means Value Added Tax
xix. "CENVAT" means Central Value Added Tax
xx. "CST" means Central Sales Tax
xxi. RR" means Railway Receipt
xxii. "BL" means Bill of Lading
xxiii. "FOB" means Free on Board
xxiv. "FOR" means Free On Road
xxv. "DAP" means Delivered At Place
xxvi. "INCOTERMS" means International Commercial Terms as on the date of TenderOpening
xxvii. "MOH&FW" means Ministry of Health & Family Welfare, Government of India.
xxviii. "AMC" means AnnualMaintenance Contract
xxix. "RT" means Re-Tender.

2. Introduction

2.1 The Purchaser has issued this TE document for purchase of goods and related services as mentioned in subsequent paragraphs which also indicates,*interalia,* the required delivery schedule, terms and place of delivery.

2.2 This section (Section II - "General Instruction Tenderers") provides the relevant information as well as instructions to assist the prospective tenderers in preparation and submission of tenders. It also includes the mode and procedure to be adopted by the purchaser for receipt and opening as well as scrutiny and evaluation of tenders and subsequent placement of contract.

2.3 The tenderers shall also read the Special Instructions to Tenderers (SIT) related to this purchase, as contained in Section III of these documents and follow the same accordingly. Whenever there is a conflict between the GIT and SIT, the provisions contained in the SIT shall prevail over those in the GIT.

2.4 Before formulating the tender and submitting the same to the purchaser, the tenderer should read and examine all the terms, conditions, instructions, checklist etc. contained in the TE

document. Failure to provide and/or comply with the required information, instructions etc. incorporated in these TE document may result in rejection of its tender.

3. Language of Tender

3.1 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, shall be written in the English language, unless otherwise specified in the Tender Enquiry. However, the language of any printed literature furnished by the tenderer in connection with its tender may be written in any other language provided the same is accompanied by an English translation and, for purposes of interpretation of the tender, the English translation shall prevail**.**

3.2 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, may also be written in the Hindi language, provided that the same are accompanied by English translation, in which case, for purpose of interpretation of the tender etc, the English translations shall prevail.

4. Eligible Tenderers

4.1 This invitation for tenders is open to all suppliers who fulfil the eligibility criteria specified against clause 16 of GIT Sec. II in this document.

5. Eligible Goods and Services

5.1 All goods and related services to be supplied under the contract shall have their origin in India or any other country with which India has not banned trade relations. The term “origin” used in this clause means the place where the goods are mined, grown, produced, or manufactured or from where the related services are arranged and supplied.

6. Tendering Expense and Tender fee

6.1 **Tender Expense:**The tenderer shall bear all costs and expenditure incurred and/or to be incurred by it in connection with its tender including preparation, mailing and submission of its tender and for subsequent processing the same. The purchaser will, in no case be responsible or liable for any such cost, expenditure etc regardless of the conduct or outcome of the tendering process.

6.2 **Tender Cost/Tenderfee:** The tenderer should submit the tender fee of USD 525.00 or equivalent amount as on tender publishing date in the form of Demand Draft or Banker’s cheque in favour of HLL Biotech limited, payable at Chennai. The DD/ Banker’s cheque has to be enclosed along with the technical bid which is non-refundable. In case of cancellation of tender by HBL, the tender cost/fee shall be refunded.

B. TENDER ENQUIRY DOCUMENTS

7. Content of Tender Enquiry Documents

7.1 In addition to Section I – “Notice inviting Tender” (NIT), the TE documents include:

- Section II – General Instructions to Tenderers (GIT)
- Section III – Special Instructions to Tenderers (SIT)
- Section IV – General Conditions of Contract (GCC)
- Section V – Special Conditions of Contract (SCC)
- Section VI – List of Requirements
- Section VII – Technical Specifications

- Section VIII – Quality Control Requirements
- Section IX – Qualification Criteria
- Section X – Tender Form
- Section XI – Price Schedules
- Section XII – Questionnaire
- Section XIII – Bank Guarantee Form for EMD
- Section XIV – Manufacturer's Authorisation Form
- Section XV – Bank Guarantee Form for Performance Security/AMC Security
- Section XVI – Contract Forms A & B
- Section XVII – Proforma of Consignee Receipt Certificate
- Section XVIII – Proforma of Final Acceptance Certificate by the consignee
- Section XIX – Check List for the Tenderers
- Section XX – Consignee List
- Section XXI - Integrity Pact
- Section XXII - Instruction of Ministry of Shipping & Transport, New Delhi, India
- Section XXIII - Schedule of Fiscal Aspects

7.2 The relevant details of the required goods and services, the terms, conditions and procedure for tendering, tender evaluation, placement of contract, the applicable contract terms and, also, the standard formats to be used for this purpose are incorporated in the above-mentioned documents. The interested tenderers are expected to examine all such details etc to proceed further.

8. Amendments to Tender Enquiry documents

8.1 At any time prior to the deadline for submission of tenders, the purchaser may, for any reason deemed fit by it, modify the TE documents by issuing suitable amendment(s) to it.

8.2 Such an amendment will be notified in the website of www.hllbiotech.com/www.lifecarehll.com / http://eprocure.gov.in/cppp.The interested parties are advised to regularly visit the website for further updates.

8.3 In order to provide reasonable time to the prospective tenderers to take necessary action in preparing their tenders as per the amendment, the purchaser may, at its discretion extend the deadline for the submission of tenders and other allied time frames, which are linked with that deadline.

9. Clarification of Tender Enquiry documents

9.1 A Tenderer requiring any clarification or elucidation on any issue of the TE documents may take up the same during the pre bid conference. The purchaser will respond to such request by publishing the response / clarification in the official websites.

C. PREPARATION OF TENDERS

10. Documents Comprising the Tender

10.1 The **Two Bid System**, i.e. "Technical Bid" and "Price Bid" prepared by the tenderer shall comprise the following:

A) Technical bid (Un priced Bid)

i. Earnest money furnished in accordance with GIT clause 18.1 alternatively, documentary evidence as per GIT clause 18.2 for claiming exemption from payment of earnest money.
ii. Tender Form as per Section X (Un priced).
iii. Documentary evidence, as necessary in terms of GIT clauses 4 and 16 establishing that the tenderer is eligible to submit the tender and, also, qualified to perform the contract if its tender is accepted.
iv. Tenderer/Agent who quotes for goods manufactured by other manufacturer shall furnish Manufacturer's Authorisation Form.
v. Power of attorney in favour of the signatory of the tender document.
vi. Documents and relevant details to establish in accordance with GIT clause 17 that the goods and the allied services to be supplied by the tenderer conform to the requirement of the TE documents.
vii. Performance Statement as per section IX along with relevant copies of orders and end users' satisfaction certificate.
viii. Price Schedule(s) as per Section XI filled up with all the details including Make, Model, etc. of the goods offered with prices blank (without indicating any prices).
ix. Certificate of country of origin by the bidder from abroad. (Chamber of commerce)
x. Checklist as per Section XIX.
xi. IRS and URS (Technical Specification) given as Annexure- I& II duly filled up and signed and stamped

B) Price Bid:

The information given at clause no. 10.1 A) ii) & viii) above should be reproduced with the prices indicated.

10.2 N.B.
1. All pages of the Tender should be page numbered and indexed.
2. It is the responsibility of tenderer to go through the TE document to ensure furnishing all required documents in addition to above, if any.

10.3 The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialled/stamped.

10.4 A tender, which does not fulfil any of the above requirements and/or gives evasive information/reply against any such requirement, shall be liable to be ignored and rejected.

10.5 Tender sent by fax/telex/cable/electronically shall be ignored.

11. Tender currencies

11.1 The tenderer supplying indigenous goods or already imported goods shall quote only in Indian Rupees.

11.2 For imported goods if supplied directly from abroad, prices shall be quoted in any freely convertible currencies say US Dollar, Euro, GBP or Yen. As regards price(s) for allied services, if any required with the goods, the same shall be quoted in Indian Rupees only if such services are to be performed /undertaken in India. Commission for Indian Agent, if any and if payable shall be indicated in the space provided for in the price schedule and will be

payable in Indian Rupees only. Such conversion of currencies will be done based on rate of exchange declared by the RBI as on the date of 'Price Bid' opening as already incorporated against clause 31 here after.

11.3 Tenders, where prices are quoted in any other way shall be treated as non -responsive and rejected.

12. Tender Prices

12.1 The Tenderer shall indicate on the Price Schedule provided under Section XI all the specified components of prices shown therein including the unit prices and total tender prices of the goods and services proposes to supply against the requirement. All the columns shown in the price schedule should be filled up as required. If any column does not apply to a tenderer, same should be clarified as "NA" by the tenderer.

12.2 The price of theschedule complete in all respect will be evaluated and the L1 party will be identified schedule wise.

12.3 The quoted prices for goods offered from within India and that for goods offered from abroad are to be indicated separately in the applicable Price Schedules attached under Section XI.

12.4 While filling up the columns of the Price Schedule, the following aspects should be noted for compliance:

12.4.1 For domestic goods or goods of foreign origin located within India, the prices in the corresponding price schedule shall be entered separately in the following manner:

a) The price of the goods, quoted ex-factory/ ex-showroom/ ex-warehouse/ off-the-shelf, as applicable, including all taxes and duties like sales tax, CST/ VAT, Customs Duty, Excise Duty etc. already paid or payable on the components and raw material used in the manufacture or assembly of the goods quoted ex-factory etc. or on the previously imported goods of foreign origin quoted ex-showroom etc;

b) Any sales or other taxes and any duties including excise duty, which will be payable on the goods in India if the contract is awarded;

c) Charges towards Packing & Forwarding, Inland Transportation, Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule would be borne by supplier;

d) The price of Incidental Services, as mentioned in List of Requirements and Price Schedule;

e) The prices of Turnkey (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and

f) The price of AMC, as mentioned in List of Requirements, Technical Specification and Price Schedule.

12.4.2 For goods offered from abroad, the prices in the corresponding price schedule shall be entered separately in the following manner:

a) The price of goods quoted DAP at Consignee Site basis,, as indicated in the List of Requirements and Price Schedule;
b) The price of goods quoted should be on DAPat Consignee Site basisin India as indicated in the List of Requirements, Price Schedule and Consignee List;
c) The prices of Turnkey (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and
d) The price of AMC (Annual Maintenance Contract), as mentioned in List of Requirements, Technical Specification and Price Schedule.

12.5 For transportation of imported goods offered from abroad, relevant instructions as incorporated under GCC Clause 10 shall be followed.

12.6 For insurance of goods to be supplied, relevant instructions as provided under GCC Clause 11 shall be followed.

12.7 Unless otherwise specifically indicated in the SCC, the terms FOB&DAPat consignee site basis in India. for imported goods offered from abroad, shall be governed by the rules & regulations prescribed in the current edition of INCOTERMS, published by the International Chamber of Commerce, Paris.

12.8 The need for indication of all such price components by the tenderers, as required in this clause (viz., GIT clause 12) is for the purpose of comparison of the tenders by the purchaser and will no way restrict the purchaser's right to award the contract on the selected tenderer on any of the terms offered.

13. Indian Agent

13.1 If a foreign tenderer has engaged an agent in India in connection with its tender, the foreign tenderer, in addition to indicating Indian agent's commission, if any, in a manner described under GIT sub clause 11.2 above, shall also furnish the following information:

a) The complete name and address of the Indian Agent and its permanent income tax account number as allotted by the Indian Income Tax authority.
b) The details of the services to be rendered by the agent for the subject requirement.
c) Details of Service outlets in India, nearest to the consignee(s), to render services during Warranty and AMC period.

14. Firm Price

14.1 Unless otherwise specified in the SIT, prices quoted by the tenderer shall remain firm and fixed during the currency of the contract and not subject to variation on any account.

15. Alternative Tenders

15.1 Alternative Tenders are not permitted.

16. Documents Establishing Tenderers Eligibility and Qualifications

16.1 Pursuant to GIT clause 10, the tenderer shall furnish, as part of its tender, relevant details and documents establishing its eligibility to quote and its qualifications to perform the contract if its tender is accepted.

16.2 The documentary evidence needed to establish the tenderer's qualifications shall fulfil the following requirements:

a) In case the tenderer offers to supply goods, which are manufactured by some other firm, the tenderer has been duly authorised by the goods manufacturer to quote for and supply the goods to the purchaser. The tenderer shall submit the manufacturer's authorization letter to this effect as per the standard form provided under Section XIV in this document.
b) The tenderer has the required financial, technical and production capability necessary to perform the contract and, further, it meets the qualification criteria incorporated in the Section IX in these documents.

c) In case the tenderer is not doing business in India, it is duly represented by an agent stationed in India fully equipped and able to carry out the required contractual functions and duties of the supplier including after sale service, maintenance & repair etc. of the goods in question, stocking of spare parts and fast moving components and other obligations, if any, specified in the conditions of contract and/or technical specifications.

d) In case the tenderer is an Indian agent/authorized representative quoting on behalf of a foreign manufacturer for the **restricted item**, the Indian agent/authorized representative is already enlisted under the Compulsory Enlistment Scheme of Ministry of Finance, Govt. of India, operated through Directorate General of Supplies & Disposals (DGS&D), New Delhi.

17. Documents establishing Goods Conformity to Tender EnquiryDocument

17.1 The tendered shall provide in its tender the required as well as the relevant documents like technical data, literature, drawings etc. to establish that the goods and services offered in the tender fully conform to the goods and services specified by the purchaser in the TE document. For this purpose the tenderer shall also provide a **clause-by-clause commentary on the technical specifications and other technical details incorporated by the purchaser in the TE Document to establish technical responsiveness of the goods and services offered in its tender**.

17.2 In case there is any variation and/or deviation between the goods & services prescribed by the purchaser and that offered by the tenderer, the tenderer shall list out the same in a chart form without ambiguity and provide the same along with its tender.

17.3 If a tenderer furnishes wrong and/or misguiding data, statement(s) etc. about technical acceptability of the goods and services offered by it, its tender will be liable to be ignored and rejected in addition toother remedies available to the purchaser in this regard.

18. Earnest Money Deposit (EMD)

18.1 Pursuant to GIT clauses 7.1 and 10.1 the tenderer shall furnish along with its tender, earnest money for amount as shown in the NIT. The earnest money is required to protect the purchaser against the risk of the tenderer's unwarranted conduct as amplified under sub-clause 18.7 below.

18.2 The tenderers who are currently registered and, also, will continue to remain registered during the tender validity period with National Small Industries Corporation, New Delhi for the specific goods as per tender enquiry specification shall be eligible for exemption from EMD. Vague stipulations in the Registration Certificate such as "to customers' specification" etc. will not be acceptable for exemption from furnishing of earnest money. In case the tenderer falls in these categories, it should furnish copy of its valid registration details (with NSIC). The EMD should be furnished in the name of **"HLL Biotech Limited, payable at** Chennai**".**

18.3 The earnest money shall be denominated in Indian Rupees or equivalent currencies as per GIT clause 11.2. The earnest money shall be furnished in one of the following forms:

Account Payee Demand Draft or Bank Guarantee

18.4 The demand draft shall be drawn on any commercial bank in India in favour of the "**HLL Biotech Limited**" payable at Chennai. If the EMD is in the form of bank guarantee, the same is to be provided from any scheduled commercial bank in India or in the case of foreign tenderer, the same should be routed through a Scheduled Commercial Bank in India as per the format specified under Section XIII of this tender.

18.5 The earnest money shall be valid for a period of forty-five (45) days beyond the validity period of the tender. As validity period of Tender as per Clause 19 of GIT is 120 days, the EMD shall be valid for 165 days from Technical Bid opening date.

18.6 Unsuccessful tenderers' earnest money will be returned to them without any interest, after expiry of the tender validity period, but not later than thirty days after conclusion of the resultant contract. Successful tenderer's earnest money will be returned without any interest, after receipt of performance security from that tenderer.

18.7 Earnest Money is required to protect the purchaser against the risk of the Tenderer's conduct, which would warrant the forfeiture of the EMD. Earnest money of a tenderer will be forfeited, if the tenderer withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged without prejudice to other rights of the purchaser. The successful tenderer's earnest money will be forfeited without prejudice to other rights of Purchaser if it fails to furnish the required performance security within the specified period.

18.8 In the case of Bank Guarantee furnished from banks outside India (i.e. foreign Banks), it should be authenticated and countersigned by any scheduled commercial bank in India, but not cooperative banks in India by way of back-to-back counter guarantee.

19. Tender Validity

19.1 If not mentioned otherwise in the SIT, the tenders shall remain valid for acceptance for a period of 120 days (One hundred and twenty days) from the date of tender opening prescribed in the TE document. Any tender valid for a shorter period shall be treated as unresponsive and rejected.

19.2 In exceptional cases, the tenderers may be requested by the purchaser to extend the validity of their tenders up to a specified period. Such request(s) and responses thereto shall be conveyed by surface mail or by fax/ telex/cable followed by surface mail. The tenderers, who agree to extend the tender validity, are to extend the same without any change or modification of their original tender and they are also to extend the validity period of the EMD accordingly. A tenderer, however, may not agree to extend its tender validity without forfeiting its EMD.

19.3 In case the day up to which the tenders are to remain valid falls on/ subsequently declared a holiday or closed day for the purchaser, the tender validity shall automatically be extended up to the next working day.

20. Signing and Sealing of Tender

20.1 The tenderers shall submit their tenders as per the instructions contained in GIT Clause 10

20.2 The tender shall either be typed or written in indelible ink and the same shall be signed by the tenderer or by a person(s) who has been duly authorized to bind the tenderer to the contract. The letter of authorization shall be by a written power of attorney, which shall also be furnished along with the tender.

20.3 The tender shall be duly signed at the appropriate places as indicated in the TE document and all other pages of the tender including printed literature, if any shall be initialled by the same person(s) signing the tender. The tender shall not contain any erasure or overwriting, except as necessary to correct any error made by the tenderer and, if there is any such correction; the same shall be initialled by the person(s) signing the tender.

20.4 The tenderer should seal the tender and write the address of the purchaser and the tender reference number on the envelope. The sentence "**NOT TO BE OPENED**before *(The tenderer is to put the date & time of tender opening)"* are to be written on these envelopes.

The inner envelopes are then to be put in a bigger outer envelope, which will also be duly sealed, marked etc. as above. If the outer envelope is not sealed and marked properly as above, the purchaser will not assume any responsibility for its misplacement, premature opening, late opening etc.

20.5 The document seeks quotation following **Two Tender System**, in two parts. First part will be known as **'Technical Bid'**, and the second part **'Price Bid'** as specified in clause 10 of GIT. Tenderer shall seal **'Technical Bid'** and **'Price Bid'** separately and covers will be suitably super scribed. Both these sealed covers shall be put in a bigger cover and sealed and procedure prescribed in Paras 20.1 to 20.4 followed.

D. SUBMISSION OF TENDERS

21. Submission of Tenders

21.1 Unless otherwise specified, the tenders are to be submitted to **The Chief Executive Officer, HLL Biotech Limited,**TicelBiopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113

21.2 The tenderers must ensure that they submit their tenders not later than the closing time and date specified for submission of tenders. It is the responsibility of the tenderer to ensure that their Tenders whether sent by post or by courier or by person,reaches the address mentioned in GIT 21.1 by the specified clearing date and time.

21.3 In the event the specified date for submission of tender falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be received up to the appointed time on the next working day.

22. Late Tender

22.1 A tender, which is received after the specified date and time for receipt of tenders will be treated as "late" tender and will be ignored and not considered.

23. Alteration and Withdrawal of Tender

23.1 The tenderer, after submitting its tender, is permitted to alter / modify its tender so long as such alterations / modifications are received duly signed, sealed and marked like the original tender, within the deadline for submission of tenders. Alterations / modifications to tenders received after the prescribed deadline will not be considered.

23.2 No tender should be withdrawn after the deadline for submission of tender and before expiry of the tender validity period. If a tenderer withdraws the tender during this period, it will result in forfeiture of the earnest money furnished by the tenderer in its tender.

E. TENDER OPENING

24. Opening of Tenders

24.1 The purchaser will open the tenders at the specified date and time and at the specified place as indicated in the NIT.

In case the specified date of tender opening falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be opened at the appointed time and place on the next working day.

24.2 Authorized representatives of the tenderers, who have submitted tenders on time may attend the tender opening provided they bring with them letters of authority from the corresponding tenderers.

The tender opening official(s) will prepare a list of the representatives attending the tender opening. The list will contain the representatives' names & signatures and corresponding tenderers' names and addresses.

24.3 Two - Tender system as mentioned in para 20.5 above will be as follows. The **Technical Bid**are to be opened in the first instance, at the prescribed time and date as indicated in NIT. These Tenders shall be scrutinized and evaluated by the competent committee/ authority with reference to parameters prescribed in the TE document. During the Technical Bid opening, the tender opening official(s) will read the salient features of the tenders like brief description of the goods offered, delivery period, Earnest Money Deposit and any other special features of the tenders, as deemed fit by the tender opening official(s). Thereafter, in the second stage, the **Price Bid** of only the Technically qualified offers **(as decided in the first stage)** shall be opened for further scrutiny and evaluation on a date notified after the evaluation of the Technical Bid. The prices, special discount if any of the goods offered etc., as deemed fit by tender opening official(s) will be read out.

F. SCRUTINY AND EVALUATION OF TENDERS

25. Basic Principle

25.1 Tenders will be evaluated on the basis of the terms & conditions already incorporated in the TE document, based on which tenders have been received and the terms, conditions etc. mentioned by the tenderers in their tenders. No new condition will be brought in while scrutinizing and evaluating the tenders.

26. Preliminary Scrutiny of Tenders

26.1 The Purchaser will examine the Tenders to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed stamped and whether the Tenders are generally in order.

26.2 Prior to the detailed evaluation of Price Bid, pursuant to GIT Clause 33, the Purchaser will determine the substantial responsiveness of each Tender to the TE Document. For purposes of these clauses, a substantially responsive Tender is one, which conforms to all the terms and conditions of the TE Documents without material deviations. Deviations from, or objections or reservations to critical provisions such as those concerning Performance Security (GCC Clause 5),Warranty (GCC Clause 15), EMD (GIT Clause 18), Taxes& Duties

(GCC Clause 20),Force Majeure (GCC Clause 26) and Applicable law (GCC Clause 31) will be deemed to be a material deviation. The Purchaser's determination of a Tender's responsiveness is to be based on the contents of the tender itself without recourse to extrinsic evidence.

26.3 If a Tender is not substantially responsive (Non-Responsive), it will be rejected by the Purchaser and cannot subsequently be made responsive by the Tenderer by correction of the nonconformity.

26.4 The tenders will be scrutinized to determine whether they are complete and meet the essential and important requirements, conditions etc. as prescribed in the TE document. The tenders, which do not meet the basic requirements, are liable to be treated as non – responsive and will be summarily ignored. A non-responsive tender is one which deviates technically or commercially from any specific provision in the tender enquiry.

26.5 The following are some of the important aspects, for which a tender shall be declared **non – responsive** and will be summarily ignored:

(i) Tender form as per Section X (signed and stamped) not enclosed
(ii) Tender is unsigned.
(iii) Tender validity is shorter than the required period.
(iv) Required EMD (Amount, validity etc.) / exemption documents have not been provided.
(v) Tenderer has quoted for goods manufactured by other manufacturer(s) without the required Manufacturer's Authorisation Form as per Section XIV.
(vi) Tenderer has not agreed to give the required performance security.
(vii) Goods offered are not meeting the tender enquiry specification.
(viii) Tenderer has not agreed to other essential condition(s) specially incorporated in the tender enquiry like terms of payment, liquidated damages clause, warranty clause, dispute resolution mechanism applicable law.
(ix) Poor/ unsatisfactory past performance.
(x) Tenderers who stand deregistered/banned/blacklisted by any Govt. Authorities.
(xi) Tenderer is not eligible as per GIT Clauses 4.1 & 16.1.
(xii) Tenderer has not quoted for the entire quantity as specified in the List of Requirements in the quoted schedule.
(xiii) The signed Integrity Pact not enclosed by the Tenderer.
(xiv) IRS and URS given in Annexure-I, II& III, not duly filled, signed and stamped.

27. Minor Infirmity /Irregularity/Non-Conformity

27.1 If during the preliminary examination, the purchaser find any minor informality and/or irregularity and/or non-conformity in a tender, the purchaser may waive the same provided it does not constitute any material deviation and financial impact and, also, does not prejudice or affect the ranking order of the tenderers. Wherever necessary, the purchaser will convey its observation on such 'minor' issues to the tenderer , asking the tenderer to respond by a specified date. If the tenderer does not reply by the specified date or gives evasive reply without clarifying the point at issue in clear terms, that tender will be liable to be ignored.

28. Discrepancies in Prices

28.1 If, in the price structure quoted by a tenderer, there is discrepancy between the unit price and the total price (which is obtained by multiplying the unit price by the quantity), the unit price shall prevail and the total price corrected accordingly, unless the purchaser feels that the tenderer has made a mistake in placing the decimal point in the unit price, in which case the total price as quoted shall prevail over the unit price and the unit price corrected accordingly.

28.2 If there is an error in a total price, which has been worked out through addition and/or subtraction of subtotals, the subtotals shall prevail and the total shall be correctedaccordingly; and

28.3 If there is a discrepancy between the amount expressed in words and figures, the amount in words shall prevail, subject to sub clause 28.1 and 28.2 above.

28.4 If, as per the judgement of the purchaser, there is any such arithmetical discrepancy in a tender, the same will be suitably conveyed to the tenderer by registered / speed post. If the tenderer does not agree to the observation of the purchaser, the tender is liable to be ignored.

29. Discrepancy between original and copies of Tender

29.1 In case any discrepancy is observed between the text etc. of the original copy and that in the other copies of the same tender set, the text etc. of the original copy shall prevail. Here also, the purchaser will convey its observation suitably to the tenderer by register / speed post and, if the tenderer does not accept the purchaser's observation, that tender will be liable to be ignored.

30. Qualification Criteria

30.1 Tenders of the tenderers, who do not meet the required Qualification Criteria prescribed in Section IX, will be treated as non - responsive and will not be considered further.

31. Conversion of tender currencies to Indian Rupees

31.1 In case the TE document permits the tenderers to quote their prices in different currencies, all such quoted prices of the responsive tenderers will be converted to a single currency viz., Indian Rupees for the purpose of equitable comparison and evaluation, as per the exchange rates established by the Reserve Bank of India for similar transactions, as on the date of 'Price bid' opening.

32. Schedule/ Package -wise Evaluation

32.1 In case the List of Requirements contains more than one schedule/ Package, the responsive tenders will be evaluated and compared separately for each schedule/package. The tender for a schedule/ package will not be considered if the complete requirements prescribed in that schedule/ package are not included in the tender. However, as already mentioned in GIT sub clause 12.2, the tenderers have the option to quote for any one or more schedules/ package.

33. Comparison of Tenders

33.1Unless mentioned otherwise in Section – III – Special Instructions to Tenderers and Section – VI – List of Requirements, the comparison of the responsive tenders shall be carried out on Delivery Duty Paid (DDP) consignee site basis. The quoted turnkey (if any) prices and AMC prices will also be added for comparison/ranking purpose for evaluation.

34. Additional Factors and Parameters for Evaluation and Ranking of Responsive Tenders

34.1 DELETED

The purchaser's evaluation of tender will also take into account the additional factors, if any, incorporated in SIT in the manner and to the extent indicated therein.

34.3 The Purchaser reserves the right to give the price preference to small-scale sectors etc. and purchase preference to central public sector undertakings as per the instruction in vogue while evaluating, comparing and ranking the responsive tenders.

35. Tenderer's capability to perform the contract

35.1 The purchaser, through the above process of tender scrutiny and tender evaluation will determine to its satisfaction whether the tenderer, whose tender has been determined as the lowest evaluated responsive tender is eligible, qualified and capable in all respects to perform the contract satisfactorily. If, there is more than one schedule/ package in the List of Requirements, then, such determination will be made separately for each schedule/ package.

35.2 The above-mentioned determination will, interalia, take into account the tenderer's financial, technical and production capabilities for satisfying all the requirements of the purchaser as incorporated in the TE document. Such determination will be based upon scrutiny and examination of all relevant data and details submitted by the tenderer in its tender as well as such other allied information as deemed appropriate by the purchaser.

36. Contacting the Purchaser

36.1 From the time of submission of tender to the time of awarding the contract, if a tenderer needs to contact the purchaser for any reason relating to this tender enquiry and / or its tender, it should do so only in writing.

36.2 In case a tenderer attempts to influence the purchaser in the purchaser's decision on scrutiny, comparison & evaluation of tenders and awarding the contract, the tender of the tenderer shall be liable for rejection in addition to appropriate administrative actions being taken against that tenderer, as deemed fit by the purchaser.

G. AWARD OF CONTRACT

37. Purchaser's Right to accept any tender and to reject any or all tenders

37.1 The purchaser reserves the right to accept in part or in full any tender or reject any or more tender(s) without assigning any reason or to cancel the tendering process and reject all tenders at any time prior to award of contract, without incurring any liability, whatsoever to the affected tenderer or tenderers.

38. Award Criteria

38.1 Subject to GIT clause 37 above, the contract will be awarded to the lowest evaluated responsive tenderer decided by the purchaser in terms of GIT Clause 35.

39. Variation of Quantities at the Time of Award/ Currency of Contract

39.1 At the time of awarding the contract, the purchaser reserves the right to increase or decrease by up tofifty (50%) per cent, the quantity of goods and services mentioned in the schedule (s) in the "List of Requirements" (rounded ofto next whole number) without any change in the unit price and other terms & conditions quoted by the tenderer.

39.2 If the quantity has not been increased at the time of the awarding the contract, the purchaser reserves the right to increase by up to fifty (50) per cent, the quantity of goods and services mentioned in the contract (rounded ofto next whole number) without any change in the unit price and other terms & conditions mentioned in the contract, during the currency of the contract after one year from the Date of Notification of Award.

40. Notification of Award

40.1 Before expiry of the tender validity period, the purchaser will notify the successful tenderer(s) in writing, by registered / speed post/ courier or by fax/telex/cable (to be confirmed by registered / speed post/courier) that its tender for goods & services, which have been selected by the purchaser, has been accepted, also briefly indicating therein the essential details like description, specification and quantity of the goods & services and corresponding prices accepted. The successful tenderer must furnish to the purchaser the required performance security within thirty days from the date of dispatch of this notification, failing which the EMD will be forfeited and the award will be cancelled. Relevant details about the performance security have been provided under GCC Clause 5 under Section IV.

40.2 The Notification of Award shall constitute the conclusion of the Contract.

41. Issue of Contract

41.1 Promptly after notification of award, the Purchaser/Consignee will mail the contract form (as per Section XVI) duly completed and signed, in duplicate, to the successful tenderer by registered / speed post/courier.

41.2 Within twenty one days from the date of the contract, the successful tenderer shall return the original copy of the contract, duly signed and dated, to the Purchaser by registered / speed post/courier.

41.3 The Purchaser- reserves the right to issue the Notification of Award consignee wise.

42. Non-receipt of Performance Security and Contract by the Purchaser/Consignee

42.1 Failure of the successful tenderer in providing performance security and / or returning contract copy duly signed in terms of GIT clauses 40 and 41 above shall make the tenderer liable for forfeiture of its EMD and, also, for further actions by the Purchaser/Consignee against it as per the clause 24 of GCC – Termination of default.

43. Return of EMD

43.1 The earnest money of the successful tenderer and the unsuccessful tenderers will be returned to them without any interest, whatsoever, in terms of GIT Clause 18.7

44. Publication of Tender Result

44.1 The name and address of the successful tenderer(s) receiving the contract(s) will be mentioned in the notice board/bulletin/web site of the purchaser.

45. Corrupt or Fraudulent Practices

45.1 It is required by all concerned namely the Consignee/Tenderers/Suppliers etc to observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the Purchaser: -

(a) defines, for the purposes of this provision, the terms set forth below as follows:

(i) "corrupt practice" means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution; and

(ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after

Tender submission) designed to establish Tender prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition;

(b) will reject a proposal for award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;

(c) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a contract by the purchaser if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing the contract.

46. Integrity Pact (IP)

The Integrity Pact (IP) will be one of the conditions in this tender enquiry. It will be considered to be a material deviation resulting into ignoring and rejecting the tender if the tenderers do not agree to accept it. The detailed terms of the IP are given below:

The Public Authority commits that:

- No official will demand or accept any illicit gratification to give any of the parties an advantage at any stage of the project.
- All necessary and appropriate technical, legal and administrative information related to the contract will be made public
- None of the officials will make available confidential information to a bidder/contractor to give unfair advantage in the contract
- Declaration by all concerned officials any conflict of interest and disclosure of own and family assets
- Officials will report to appropriate government authority about any breach/attempt to breach a commitment.

The Bidder commits that:

- they will not offer any illicit gratification to obtain unfair advantage
- they will not collude with other parties to impair transparency and fairness
- they will not accept any advantage in exchange for unprofessional behavior
- will disclose all payments made to agents and intermediaries
- it will demonstrate existence of organization-wide code of conduct forbidding unethical practices

Penalties:

For failure to implement IP, officials will be subject to penal action and bidders will face cancellation of contract, forfeiture of bond, liquidated damages and blacklisting. Action will not require criminal conviction but be based on “no-contest” after the evidence is made available or there can be no material doubts. Disputes in IP implementation would be resolved by arbitration detailed in IP.

Integrity Pact has to be signed and submitted by the Tenderer along with the filled up Tenders, failing which the Tender is liable to be rejected. Integrity Pactis enclosed in Section-XXI

47. Paying Authority:

47.1 The payment for the supplies of stores / goods / equipments which including agency commission, turnkey (if any), installation and commissioning and any other payment mentioned in the tender enquiry will be made by “**HLL Biotech Limited”**.

SECTION - III
SPECIAL INSTRUCTIONS TO TENDERERS (SIT)

Sl. No.	GIT Clause No.	Topic	SIT Provision
A	1 to 6	Preamble	No Change
B	7 to 9	TE documents	No Change
C	10 to 17,19,20	Preparation of Tenders	No Change
D	21 to23	Submission of Tenders	No Change
E	24	Tender Opening	No Change
F	25 to 33, 35,36	Scrutiny and Evaluation of Tenders	No Change
G	37 to 47	Award of Contract	No Change

In case of any conflict between the provision in the GIT and that in the SIT, the provision contained in the SIT shall prevail.

18. MSE units who are registered and also will continue to remain registered during the tender validity period with NSIC are exempted from payment of Bid security (EMD) and other benefits as applicable, but authenticated copy of the valid NSIC certificate for tendered item(s) should be submitted along with Technical Bid of the Tender to qualify for such exemptions and other benefits.

34. The tenderer shall necessarily quote for all the items of the relevant Price Schedules (Section XI A to XI D) of the Tender, failing which the Purchaser reserves the right to disqualify and reject the tenderer.

SECTION - IV

GENERAL CONDITIONS OF CONTRACT (GCC)
TABLE OF CLAUSES

SECTION - IV
GENERAL CONDITIONS OF CONTRACT (GCC)

1. Application

1.1 The General Conditions of Contract incorporated in this section shall be applicable for this purchase to the extent the same are not superseded by the Special Conditions of Contract prescribed under Section V, List of requirements under Section VI and Technical Specification under Section VII of this document.

2. Use of contract documents and information

2.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract or any provision thereof including any specification, drawing, sample or any information furnished by or on behalf of the purchaser in connection therewith, to any person other than the person(s) employed by the supplier in the performance of the contract emanating from this TE document. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for the purposes of such performance for this contract.

2.2 Further, the supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC sub-clause 2.1 above except for the sole purpose of performing this contract.

2.3 Except the contract issued to the supplier, each and every other document mentioned in GCC sub-clause 2.1 above shall remain the property of the purchaser and, if advised by the purchaser, all copies of all such documents shall be returned to the purchaser on completion of the supplier's performance and obligations under this contract.

3. Patent Rights

3.1 The supplier shall, at all times, indemnify and keep indemnified the purchaser, free of cost, against all claims which may arise in respect of goods & services to be provided by the supplier under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks. In the event of any such claim in respect of alleged breach of patent, registered designs, trade marks etc. being made against the purchaser, the purchaser shall notify the supplier of the same and the supplier shall, at his own expenses take care of the same for settlement without any liability to the purchaser.

4. Country of Origin

4.1 All goods and services to be supplied and provided for the contract shall have the origin in India or in the countries with which the Government of India has trade relations.

4.2 The word "origin" incorporated in this clause means the place from where the goods are mined, cultivated, grown, manufactured, produced or processed or from where the services are arranged.

4.3 The country of origin may be specified in the Price Schedule

5. Performance Security

5.1 Withinten (10) days from date of the issue of notification of award by the Purchaser/Consignee, the supplier, shall furnish performance security to the Purchaser/Consignee for an amount equal to five percent (5%) of the total value of the contract, valid up to sixty (60) days after the date of completion of all contractual obligations

by the supplier, including the warranty obligations, initially valid for a period of minimum 27 months from the date of Notification of Award

5.2 The Performance security shall be denominated in Indian Rupees or in the currency of the contract as detailed below:

a) It shall be in the form of Bank Guarantee issued by a Scheduled Commercial bank in India or in the case of a foreign tenderer, the same shall be routed through a Scheduled Commercial Bank, in the prescribed form as provided in section XV of this document in favour of the Purchaser. The validity of the Fixed Deposit receipt or Bank Guarantee will be for a period up to sixty (60) days beyond Warranty Period.

5.3 In the event of any failure /default of the supplier with or without any quantifiable loss to the government including furnishing of Bank Guarantee for AMC security as per Proforma in Section XV, the amount of the performance security is liable to be forfeited.

5.4 In the event of any amendment issued to the contract, the supplier shall, within twenty-one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary), rendering the same valid in all respects in terms of the contract, as amended.

5.5 The supplier shall enter into Annual Maintenance Contract as per the 'Contract Form – B' in Section XVI with the Consignee/Client, 3 (three) months prior to the completion of Warranty Period. The AMC will commence from the date of expiry of the Warranty Period.

5.6 Subject to GCC sub – clause 5.3 above, the Purchaser/Consignee will release the Performance Security without any interest to the supplier on completion of the supplier's all contractual obligations including the warranty obligations & after receipt of Consignee wise (in the case of more than one consignee) bank guarantee for AMC security in favour of the consignee as per the format in Section XV within 10 days from the date of AMC contract form signed. The supplier, shall furnish performance security to the Purchaser/Consignee for an amount equal to five percent (5%) of the total AMC value for 2 years in the form of DD/ Bank Guarantee from any scheduled commercial bank which shall be valid till completion of AMC period (2 years) with the additional claim period of 2 months.

6. Technical Specifications and Standards

6.1 The Goods & Services to be provided by the supplier under this contract shall conform to the technical specifications and quality control parameters mentioned in 'Technical Specification'; 'Quality Control Requirements' under Sections VII and Section VIII of this document and URS enclosed as annexure to this document.

7. Packing and Marking

7.1 The packing for the goods to be provided by the supplier should be strong and durable enough to withstand, without limitation, the entire journey during transit including transhipment (if any), rough handling, open storage etc. without any damage, deterioration etc. As and if necessary, the size, weights and volumes of the packing cases shall also take into consideration, the remoteness of the final destination of the goods and availability or otherwise of transport and handling facilities at all points during transit up to final destination as per the contract.

7.2 The quality of packing, the manner of marking within & outside the packages and provision of accompanying documentation shall strictly comply with the requirements as provided in Technical Specifications and Quality Control Requirements under Sections VII and VIII and in SCC under Section V. In case the packing requirements are amended due to issue of any amendment to the contract, the same shall also be taken care of by the supplier accordingly.

7.3 Packing instructions:

Unless otherwise mentioned in the Technical Specification and Quality Control Requirements under Sections VII and Section VIII and in SCC under Section V, the supplier shall make separate packages for each consignee (in case there is more than one consignee mentioned in the contract) and mark each package on three sides with the following with indelible paint of proper quality:

a. contract number and date

b. brief description of goods including quantity

c. packing list reference number

d. country of origin of goods

e. consignee's name and full address and

f. supplier's name and address

8. Inspection, Testing and Quality Control

8.1 The purchaser and/or its nominated representative(s) will, without any extra cost to the purchaser, inspect and/or test (FAT) the ordered goods and the related services to confirm their conformity to the contract specifications and other quality control details incorporated in the contract. The purchaser shall inform the supplier in advance, in writing, the purchaser's programme for such inspection (FAT) and, also the identity of the officials to be deputed for this purpose. The cost towards the transportation, boarding & lodging will be borne by the purchaser and/or its nominated representative(s).

8.2 The Technical Specification and Quality Control Requirements incorporated in the contract / URS shall specify what inspections and tests are to be carried out and, also, where and how they are to be conducted. If such inspections and tests are conducted in the premises of the supplier or its subcontractor(s), all reasonable facilities and assistance, including access to relevant drawings, design details and production data, shall be furnished by the supplier to the purchaser's inspector at no charge to the purchaser.

8.3 If during such inspections (FAT) and tests the contracted goods fail to conform to the required specifications and standards, the purchaser's inspector may reject them and the supplier shall either replace the rejected goods or make all alterations necessary to meet the specifications and standards, as required, free of cost to the purchaser and resubmit the same for conducting the inspections and tests again.

8.4 In case the contract stipulates pre-despatch inspection of the ordered goods at supplier's premises, the supplier shall put up the goods for such inspection to the purchaser's inspector well ahead of the contractual delivery period, so that the purchaser's inspector is able to complete the inspection within the contractual delivery period.

8.5 If the supplier tenders the goods to the purchaser's inspector for inspection at the last moment without providing reasonable time to the inspector for completing the inspection within the contractual delivery period, the inspector may carry out the inspection and complete the formality beyond the contractual delivery period at the risk and expense of the supplier. The fact that the goods have been inspected after the contractual delivery period will not have the effect of keeping the contract alive and this will be without any prejudice to the legal rights and remedies available to the purchaser under the terms & conditions of the contract.

8.6 The purchaser's/consignee's contractual right to inspect, test and, if necessary, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by purchaser's inspector during pre-despatch inspection mentioned above.

8.7 Goods accepted by the purchaser/consignee and/or its inspector at initial inspection and in final inspection in terms of the contract shall in no way dilute purchaser's/consignee's right to reject the same later, if found deficient in terms of the warranty clause of the contract, as incorporated under GCC Clause 15.

8.8 If stipulated by the Purchaser, the Principal/ Foreign or Domestic suppliers shall also have the equipment inspected by recognised/ reputed agency like SGS, Lloyd or equivalent (acceptable to the purchaser) prior to despatch at the supplier's cost and furnish necessary certificate from the said agency in support of their claim.

9. Terms of Delivery

9.1 Goods shall be delivered by the supplier in accordance with the terms of delivery specified in the **Schedule of Fiscal Aspects.**

10. Transportation of Goods

10.1 Instructions for transportation of imported goods offered from abroad:

The supplier shall not make part-shipments and/or transhipment without the express/prior written consent of the purchaser. The supplier is required under the contract to deliver the goods under DAP at consignee site basis.

10.2 Transportation of domestic goods including goods already imported by the supplier to be done by the supplier himself and the goods to be delivered at the site of the consignee at his own cost.

11. Insurance:

11.1 Unless otherwise instructed in the SCC, the supplier shall make arrangements for insuring the goods against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the following manner:

I. In case of supply of domestic goods on consignee site basis, the supplier shall be responsible till the entire stores contracted for arrival in good condition at destination. The transit risk in this respect shall be covered by the Supplier by getting the stores duly insured. The insurance cover shall be obtained by the Supplier and should be valid till 3 months after the receipt of goods by the consignee.

II. In case of supply of the imported goods on CIP Named port of Destination Basis, the additional extended Insurance (local transportation and storage) would be borne by the Supplier from the port of entry to the consignee site for a period including 3 months beyond date of delivery.

11.2 If the equipment is not commissioned and handed over to the consignee within 3 months, the insurance will be extended by the supplier at their own cost till the successful installation, testing, commissioning, qualification and handing over of the goods to the consignee. In case the delay in the installation and commissioning is due to handing over of the site to the supplier by the consignee, such extensions of the insurance will still be done by the supplier, but the insurance extension charges at actuals will be reimbursed.

12. Spare parts

12.1 If specified in the List of Requirements and in the resultant contract, the supplier shall supply/provide any or all of the following materials, information etc. pertaining to spare parts manufactured and/or supplied by the supplier:

a) The spare parts as selected by the Purchaser/Consignee to be purchased from the supplier, subject to the condition that such purchase of the spare parts shall not relieve the supplier of any contractual obligation including warranty obligations; and

b) In case the production of the spare parts is discontinued:

- Sufficient advance notice to the Purchaser/Consignee before such discontinuation to provide adequate time to the purchaser to purchase the required spare parts etc., and
- Immediatelyfollowing such discontinuation, providing the Purchaser/Consignee, free of cost, the designs, drawings, layouts and specifications of the spare parts, as and if requested by the Purchaser/Consignee.

12.2 Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spares for the goods so that the same are supplied to the Purchaser/Consignee promptly on receipt of order from the Purchaser/Consignee.

13. Incidental services

13.1 Subject to the stipulation, if any, in the SCC (Section – V), List of Requirements (Section – VI) and the Technical Specification (Section – VII), the supplier shall be required to perform the following services.

- Installation & commissioning, Supervision and Demonstration of the goods
- Providing required jigs and tools for assembly, minor civil works required for the completion of the installation.
- Training of Consignee for operating and maintaining the goods
- Supplying required number of operation & maintenance manual for the goods

14. Distribution of Dispatch Documents for Clearance/Receipt of Goods

The supplier shall send all the relevant despatch documents well in time to the Purchaser/Consignee to enable the Purchaser/Consignee clear or receive (as the case may be) the goods in terms of the contract.
Unless otherwise specified in the SCC, the usual documents involved and the drill to be followed in general for this purpose are as follows.

A) For Domestic Goods, including goods already imported by the supplier under its own arrangement

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract):

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
(ii) Two copies of packing list identifying contents of each package;
(iii) Inspection certificate issued by the nominated Inspection agency, if any.
(iv) Certificate of origin;
(v) Insurance Certificate as per GCC Clause 11.
(vi) Manufacturers/Supplier's warranty certificate & In-house inspection certificate.

B) For goods imported from abroad

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract).

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Original and four copies of the negotiable clean, on-board Bill of Lading/Airway bill, marked freight pre paid and four copies of non-negotiable Bill of Lading/Airway bill;

(iii) Four Copies of packing list identifying contents of each package;

(iv) Manufacturer's/Supplier's warranty certificate;

(v) Certificate of origin

(vi) Insurance Certificate as per GCC Clause 11

(vii) Port of Loading;

(viii) Port of Discharge and

(ix) Expected date of arrival.

15. Warranty

15.1 The supplier warrantscomprehensivelythat the goods supplied under the contract is new, unused and incorporate all recent improvements in design and materials unless prescribed otherwise by the purchaser in the contract. The supplier further warrants that the goods supplied under the contract shall have no defect arising from design, materials (*except when the design adopted and / or the material used are as per the Purchaser's/Consignee's specifications*) or workmanship or from any act or omission of the supplier, that may develop under normal use of the supplied goods under the conditions prevailing in India.

15.2 This warranty shall remain valid for 1(one) year after the goods or any portion thereof as the case may be, have been delivered to the final destination and installed and commissioned at the final destination and accepted by the Purchaser/Consignee in terms of the contract, unless specified otherwise in the SCC.

a. No conditional warranty like mishandling, manufacturing defects etc. will be acceptable.

b. Warranty as well as Comprehensive Maintenance contract will be inclusive of all accessories and Turnkey (if any) work and it will also cover all wearable & non wearable components.

c. Replacement and repair will be under taken for the defective goods.

d. Proper marking has to be made for all spares for identification like printing of installation and repair dates.

15.3 In case of any claim arising out of this warranty, the Purchaser/Consignee shall promptly notify the same in writing to the supplier. The period of the warranty will be as per G.C.C clause number 15.2 above irrespective of any other period mentioned elsewhere in the bidding documents.

15.4 Upon receipt of such notice, the supplier shall, within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis respond to take action and to repair or replace the defective goods or parts thereof, free of cost, at the ultimate destination within 48 hours. The supplier shall take over the replaced parts/goods after providing their replacements and no claim, whatsoever shall lie on the purchaser for such replaced parts/goods thereafter. The penalty clause for non rectification will be applicable as per tender conditions.

15.5 In the event of any rectification of a defect or replacement of any defective goods during the warranty period, the warranty for the rectified/replaced goods shall be extended to a further period of twenty four (24) months from the date such rectified / replaced goods starts functioning to the satisfaction of the purchaser.

15.6 If the supplier, having been notified, fails to respond to take action to repair or replace the defect(s) within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis, the purchaser may proceed to take such remedial action(s) as deemed fit by the purchaser, at the risk and

expense of the supplier and without prejudice to other contractual rights and remedies, which the purchaser may have against the supplier.

15.7 During Warranty period, the supplier is required to visit consignee's site at least once in 3 months commencing from the date of the installation for preventive maintenance of the goods.

15.8 The Purchaser/Consignee reserve the rights to enter into Annual Maintenance Contract between Consignee and the Supplier for the period as mentioned in Section VII, Technical Specifications after the completion of warranty period.

15.9 The supplier along with its Indian Agent and the AMC provider shall ensure continued supply of the spare parts for the machines and equipments supplied by them to the purchaser for 10 years from the date of installation and handing over.

15.10 The Supplier along with its Indian Agent and the AMC Provider shall always accord most favoured client status to the Purchaser vis-à-vis its other Clients/Purchasers of its equipments/machines/goods etc. and shall always give the most competitive price for its machines/equipments supplied to the Purchaser/Consignee.

16. Assignment

16.1 The Supplier shall not assign, either in whole or in part, its contractual duties, responsibilities and obligations to perform the contract, except with the Purchaser's prior written permission.

17. Sub Contracts

17.1 The Supplier shall notify the Purchaser in writing of all sub contracts awarded under the contract if not already specified in its tender. Such notification, in its original tender or later, shall not relieve the Supplier from any of its liability or obligation under the terms and conditions of the contract.

17.2 Sub contract shall be only for bought out items and sub-assemblies.

17.3 Sub contracts shall also comply with the provisions of GCC Clause 4 ("Country of Origin").

18. Modification of contract

18.1 If necessary, the purchaser may, by a written order given to the supplier at any time during the currency of the contract, amend the contract by making alterations and modifications within the general scope of contract in any one or more of the following:

a) Specifications, drawings, designs etc. where goods to be supplied under the contract are to be specially manufactured for the purchaser,

b) Mode of packing,

c) Incidental services to be provided by the supplier

d) Mode of despatch,

e) Place of delivery, and

f) Any other area(s) of the contract, as felt necessary by the purchaser depending on the merits of the case.

18.2 In the event of any such modification/alteration causing increase or decrease in the cost of goods and services to be supplied and provided, or in the time required by the supplier to perform any obligation under the contract, an equitable adjustment shall be made in the contract price and/or contract delivery schedule, as the case may be, and the contract amended accordingly. If the supplier doesn't agree to the adjustment made by the Purchaser/Consignee, the supplier shall convey its views to the Purchaser/Consignee within

twenty-one days from the date of the supplier's receipt of the Purchaser's/Consignee's amendment / modification of the contract.

19. Prices

19.1 Prices to be charged by the supplier for supply of goods and provision of services in terms of the contract shall not vary from the corresponding prices quoted by the supplier in its tender.

20. Taxes and Duties

20.1 Supplier shall be entirely responsible for all taxes, duties, fees, levies etc. incurred until delivery of the contracted goods to the purchaser.

20.2 Further instruction, if any, shall be as provided in the SCC.

20.3 No exemption certificate will be provided by the consignee for customs duty, central Excise duty etc.

20.4 HBL will issue a 'C' form for interstate sale.

20.5 The entry tax, if applicable, the exemption certificate will be issued.

21. Terms and Mode of Payment

21.1 Payment Terms

Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of contract in the following manner.

A) Payment for Domestic Goods Or Foreign Origin Located Within India.

Payment shall be made in Indian Rupees as specified in the contract in the following manner:

a) Advance

An advance of 10% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 5 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) On delivery at site:

70 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;

(iii) Two copies of packing list identifying contents of each package;

(iv) Dispatch Clearance from Purchaser or authorized agent

(v) Inspection certificate issued by the nominated Inspection agency, if any.

(vi) Insurance Certificate as per GCC Clause 11

(vii) Certificate of Country of origin.

c) On Installation Qualification (IQ) & Submission of IQ report by client/ purchaser

5% of the contract Value

d) On Operational Qualification (OQ) & submission of OQ report by client/ purchaser

5% of the Contract Value

e) On validation and Final Acceptance Certificate by Client/ Purchaser:

Balance 10 % payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchasersubject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

B) Payment for Imported Goods:

Payment against Imported goods shall be made in the currency through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the supplier in a bank in his country as specified in the contract in the following manner:

a) Advance

10% of the net DAP price after submission of Bank guarantee equivalent to 110% of the advance amount in the same currency along with submission of Security Deposit / Performance security equal to 5% of the contract value in the form of a bank guarantee from or in the case of a foreign tenderer, the same shall be endorsed by a Scheduled Commercial Bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) On Receipt of Goods at site:

70% of the net DAPprice DAP price less Indian Agency commission) of the goods delivered shall be paid and upon submission of documents specified hereunder:

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Original and four copies of the negotiable clean, on-board Bill of Lading/ Airway bil , marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;

(iii) Four Copies of packing list identifying contents of each package;

(iv) Documents to be submitted for payment of LC, confirming that dispatch documents has already been sent to all concerned as per the contract within 24 hours;

(v) Insurance Certificate as per GCC Clause 11.

(vi) Manufacturer's/Supplier's warranty certificate;

(vii) Manufacturer's own factory inspection report and

(viii) Certificate of origin by the chamber of commerce of the concerned country;

(ix) Goods receipt certificate by the ultimate consignee on receipt of goods at this site/warehouse as per section XVII of this tender document.

c) On Installation Qualification (IQ) & Submission of IQ report by client/ purchaser

5% of the net DAPprice

d) On Operational Qualification (OQ) & submission of OQ report by client/ purchaser

5% of the net DAPprice

e) On validation and Final Acceptance Certificate by Client/ Purchaser:

Balance 10 % of the net DAPprice payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to

be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

f) Payment of **incidental services (including installation & commissioning, supervision, demonstration and training)** will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative or to the principal in their currency.

g) Payment of customs clearance and handling charges, loading/ unloading, inland transportation, incidental costs till consignee site will be paid in Indian Rupees to the Manufacturer's Authorized Indian representativeor to the principal in their currency on intimation to the purchaser with Bill of Entry and supporting documents. HoweverCustoms duty will be paid in Indian Rupees to the customs department directly by HBL on intimation by the vendor's Customs Clearing Agent with demand notice / Assessment order from Customs.

h) Payment of Indian Agency Commission:

Indian Agency commission will be paid to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule (as per prevailing rate of exchange ruling on the date of Contract) and shall not be subject to further escalation / exchange variation. 100% Payment shall be paid in Indian Rupees to the Indian Agent after 100 % paymentto the foreign principal.

i) Payment for services:

In case of separate service order issued to the vendor, the payment shall be as below:

a. 50% of service order value against installation
b. 30% of service order value against commissioning
c. Balance 20% of service order value against Final Acceptance Certificate by Client/ Purchaser

C) Payment of Turnkey (if any) (TENDER FOR SUPPLY, INSTALLATION,COMMISSIONING AND VALIDATION OF LYOPHILIZERS):

Turnkey payment (if any) will be made to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule.

Payment of Turnkey (if any) shall be made in the following stages:

d. 50% against installation
e. 30% against commissioning
f. Balance 20% against Final Acceptance Certificate by Client/ Purchaser.

D) Payment for Annual Maintenance Contract Charges:

The Consignee/Client will enter into AMC with the supplier at the rates as stipulated in the contract, three months prior to completion of warranty period. The payment of AMC will be made on half yearly basis after satisfactory completion of said period, duly certified by the consignee.

However entering into an agreement on AMC with the Supplier on completion of warranty period is the sole discretion of the Client

21.2 The supplier shall not claim any interest on payments under the contract.

21.3 Where there is a statutory requirement for tax deduction at source, such deduction towards income tax and other tax as applicable will be made from the bills payable to the Supplier at rates as notified from time to time.

21.4 Irrevocable & non – transferable LC shall be opened by the Purchaser. However, if the supplier requests specifically to open confirmed LC, the extra charges would be borne by the supplier. If LC is required to be extended and/or amended for reasons not attributable to the purchaser/consignee, the charges thereof shall be borne by the supplier.

21.5 The payment shall be made in the currency / currencies authorised in the contract.

21.6 The supplier shall send its claim for payment in writing, when contractually due, along with relevant documents etc., duly signed with date, to the purchaser.

21.7 While claiming payment, the supplier has also to certify in the bill that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the supplier for claiming that payment has been fulfilled as required under the contract.

21.8 In case where the supplier is not in a position to submit its bill for the balance payment for want of receipted copies of Inspection Note from the consignee and the consignee has not complained about the non-receipt, shortage, or defects in the supplies made, balance amount will be paid by the paying authority without consignee's receipt certificate after three months from the date of the preceding part payment for the goods in question, subject to the following conditions:

(a) The supplier will make good any defect or deficiency that the consignee (s) may report within six months from the date of despatch of goods.
(b) Delay in supplies, if any, has been regularized.
(c) The contract price where it is subject to variation has been finalized.
(d) The supplier furnishes the following undertakings:

"I/We, _____ certify that I/We have not received back the Inspection Note duly receipted by the consignee or any communication from the purchaser or the consignee about non-receipt, shortage or defects in the goods supplied. I/We _____ agree to make good any defect or deficiency that the consignee may report within three months from the date of receipt of this balance payment.

22. Delay in the supplier's performance

22.1 The supplier shall deliver the goods and perform the services under the contract within the time schedule specified by the Purchaser/Consignee in the List of Requirements and as incorporated in the contract.

22.2 Subject to the provision under GCC clause 26, any unexcused delay by the supplier in maintaining its contractual obligations towards delivery of goods and performance of services shall render the supplier liable to any or all of the following sanctions:

(i) Imposition of liquidated damages,

(ii) Forfeiture of its performance security and

(iii) Termination of the contract for default.

22.3 If at any time during the currency of the contract, the supplier encounters conditions hindering timely delivery of the goods and performance of services, the supplier shall promptly inform the Purchaser/Consignee in writing about the same and its likely duration and make a request to the Purchaser/Consignee for extension of the delivery schedule accordingly. On receiving the supplier's communication, the Purchaser/Consignee shall examine the situation as soon as possible and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages for completion of supplier's contractual obligations by issuing an amendment to the contract.

22.4 When the period of delivery is extended due to unexcused delay by the supplier, the amendment letter extending the delivery period shall, interalia contain the following conditions:

a. The Purchaser/Consignee shall recover from the supplier, under the provisions of the clause 23 of the General Conditions of Contract, liquidated damages on the goods and services, which the Supplier has failed to deliver within the delivery period stipulated in the contract.

b. That no increase in price on account of any ground, whatsoever, including any stipulation in the contract for increase in price on any other ground and, also including statutory increase in or fresh imposition of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or on account of any other tax or duty which may be levied in respect of the goods and services specified in the contract, which takes place after the date of delivery stipulated in the contract shall be admissible on such of the said goods and services as are delivered and performed after the date of the delivery stipulated in the contract.

c. But nevertheless, the Purchaser/Consignee shall be entitled to the benefit of any decrease in price on account of reduction in or remission of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or any other duty or tax or levy or on account of any other grounds, which takes place after the expiry of the date of delivery stipulated in the contract.

22.5 The supplier shall not dispatch the goods after expiry of the delivery period. The supplier is required to apply to the Purchaser/Consignee for extension of delivery period and obtain the same before despatch. In case the supplier dispatches the goods without obtaining an extension, it would be doing so at its own risk and no claim for payment for such supply and / or any other expense related to such supply shall lie against the purchaser.

23. Liquidated damages

23.1 Subject to GCC clause 26, if the supplier fails to deliver any or all of the goods or fails to perform the services within the time frame(s) incorporated in the contract, the Purchaser/Consignee shall, without prejudice to other rights and remedies available to the Purchaser/Consignee under the contract, deduct from the contract price, as liquidated damages, a sum equivalent to 0.5% per week of delay or part thereof on delayed supply of goods and/or services until actual delivery or performance subject to a maximum of 5% of the contract value. Once the maximum is reached Purchaser/Consignee may consider termination of the contract as per GCC 24.

During the above-mentioned delayed period of supply and / or performance, the conditions incorporated under GCC sub-clause 22.4 above shall also apply.

24. Termination for default

24.1 The Purchaser/Consignee , without prejudice to any other contractual rights and remedies available to it (the Purchaser/Consignee), may, by written notice of default sent to the supplier, terminate the contract in whole or in part, if the supplier fails to deliver any or all of the goods or fails to perform any other contractual obligation(s) within the time period specified in the contract, or within any extension thereof granted by the Purchaser/Consignee pursuant to GCC sub-clauses 22.3 and 22.4.

24.2 In the event of the Purchaser/Consignee terminates the contract in whole or in part, pursuant to GCC sub-clause 24.1 above, the Purchaser/Consignee may procure goods and/or services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the supplier shall be liable to the Purchaser/Consignee for the extra expenditure, if any, incurred by the Purchaser/Consignee for arranging such procurement.

24.3 Unless otherwise instructed by the Purchaser/Consignee, the supplier shall continue to perform the contract to the extent not terminated.

25. Termination for insolvency

25.1 If the supplier becomes bankrupt or otherwise insolvent, the purchaser reserves the right to terminate the contract at any time, by serving written notice to the supplier without any compensation, whatsoever, to the supplier, subject to further condition that such termination will not prejudice or affect the rights and remedies which have accrued and / or will accrue thereafter to the Purchaser/Consignee.

26. Force Majeure

26.1 Notwithstanding the provisions contained in GCC clauses 22, 23 and 24, the supplier shall not be liable for imposition of any such sanction so long the delay and/or failure of the supplier in fulfilling its obligations under the contract is the result of an event of Force Majeure.

26.2 For purposes of this clause, Force Majeure means an event beyond the control of the supplier and not involving the supplier's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the Purchaser/Consignee either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees , lockouts excluding by its management, and freight embargoes.

26.3 If a Force Majeure situation arises, the supplier shall promptly notify the Purchaser/Consignee in writing of such conditions and the cause thereof within twenty one days of occurrence of such event. Unless otherwise directed by the Purchaser/Consignee in writing, the supplier shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26.4 If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side.

26.5 In case due to a Force Majeure event the Purchaser/Consignee is unable to fulfil its contractual commitment and responsibility, the Purchaser/Consignee will notify the supplier accordingly and subsequent actions taken on similar lines described in above sub-paragraphs.

27. Termination for convenience

27.1 The Purchaser/Consignee reserves the right to terminate the contract, in whole or in part for its (Purchaser's/Consignee 's) convenience, by serving written notice on the supplier at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the Purchaser/Consignee. The notice shall also indicate interalia, the extent to which the supplier's performance under the contract is terminated, and the date with effect from which such termination will become effective.

27.2 The goods and services that are complete and ready in terms of the contract for delivery and performance within thirty days after the supplier's receipt of the notice of termination shall be accepted by the Purchaser/Consignee following the contract terms, conditions and prices. For the remaining goods and services, the Purchaser/Consignee may decide:

a) To get any portion of the balance completed and delivered at the contract terms, conditions and prices; and / or

b) To cancel the remaining portion of the goods and services and compensate the supplier by paying an agreed amount for the cost incurred by the supplier towards the remaining portion of the goods and services.

28. Governing language

28.1 The contract shall be written in English language following the provision as contained in GIT clause 3. All correspondence and other documents pertaining to the contract, which the parties exchange, shall also be written accordingly in that language.

29. Notices

29.1 Notice, if any, relating to the contract given by one party to the other, shall be sent in writing or by cable or telex or facsimile and confirmed in writing. The procedure will also provide the sender of the notice, the proof of receipt of the notice by the receiver. The addresses of the parties for exchanging such notices will be the addresses as incorporated in the contract.

29.2 The effective date of a notice shall be either the date when delivered to the recipient or the effective date specifically mentioned in the notice, whichever is later.

30. Resolution of disputes

30.1 If dispute or difference of any kind shall arise between the Purchaser/Consignee and the supplier in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

30.2 If the parties fail to resolve their dispute or difference by such mutual consultation within twenty-one days of its occurrence, then, unless otherwise provided in the SCC, either the Purchaser/Consignee or the supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided the applicable arbitration procedure will be as per the Arbitration and Conciliation Act, 1996 of India. In the case of a dispute or difference arising between the Purchaser/Consignee and a domestic Supplier relating to any matter arising out of or connected with the contract, such dispute or difference shall be referred to the sole arbitrator appointed by the Chairman of HBL.The award of arbitrator shall be final and binding on the parties to the contract.

30.3 Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

31. Applicable Law

a. The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

b. Jurisdiction

The courts at Chennai, Tamil Nadu shall have exclusive jurisdiction for all disputesand difference arising out of this contract.

32. General/ Miscellaneous Clauses

32.1 Nothing contained in this Contract shall be constructed as establishing or creating between the parties, i.e. the Supplier/its Indian Agent/AMC Provider on the one side and the Purchaser on the other side, a relationship of master and servant or principal and agent.

32.2 Any failure on the part of any Party to exercise right or power under this Contract shall not operate as waiver thereof.

32.3 The Supplier shall notify the Purchaser/Consignee /the Government of India of any material change would impact on performance of its obligations under this Contract.

32.4 Each member/constituent of the Supplier/its Indian Agent/AMC Provider, shall be **jointly and severally liable** to and responsible for all obligations towards the Purchaser/Consignee/Government for performance of contract/services including that of its Associates/Sub Contractors under the Contract.

32.5 **Indemnities**

32.5.1 The Supplier/its Indian Agent/AMC Provider shall at all times, indemnify and keep indemnified the Purchaser/Government of India against all claims, damages, cost and expenses arising from the incorporation in or use of work of any such articles, processes or supplies made under this agreement. Supplier shall at all times indemnify the purchaser against all claims which may be madefor any infringement of any Intellectual Property Rights (IPR) while providing its services under AMC or the Contract.

32.5.2 The Supplier/its Agent/AMC Provider shall, at all times, indemnify and keep indemnified the Purchaser/Consignee/Government of India against any claims in respect of any damages or compensation payable in consequences of any accident or injury sustained or suffered by itsemployees or agents or by any other third party resulting from or by any action, omission or operation conducted by or on behalf of the supplier/its associate/affiliate etc.

SECTION – V

SPECIAL CONDITIONS OF CONTRACT (SCC)

The following Special Conditions of Contract (SCC) will apply for this purchase..

These Special Conditions will modify/substitute/supplement the corresponding (GCC) clauses.

Whenever there is any conflict between the provision in the GCC and that in the SCC, the provision contained in the SCC shall prevail.

20. Taxes and Duties

Any variation in statutory levies/taxes within the contractual delivery period shall be to HBL's account subject to production of documentary evidence and Govt. notifications by the Supplier & beyond contractual delivery period, upward variation shall be to Supplier's account. Unit Prices quoted by the bidder shall be firm and valid, irrespective of any statutory variations in Taxes/levies.
In case any taxes, duties are not clearly specified in price bid then it will be presumed that no such tax/levy is applicable or payable. Blank field in Price Bid shall be treated as 'Inclusive' in the quoted price.

SECTION - VI
LIST OF REQUIREMENTS

Schedul. No	EQUIPMENTS	Equipment ID	Capacity / Size	QTY	EMD
I	Lyophilizer	F1-LYO 01	$10m^2$: 40,000 vials/batch (2R)	1	Rs. 2.87 Million
		F1-LYO 02	$20m^2$: 80,000 vials / batch (4R)	1	

Part II:Required Delivery Schedule:

As mentioned in the schedule of Fiscal Aspects

Part III: Scope of Incidental Services:

Installation & Commissioning, Supervision, Demonstration, Trial run and Training etc. as specified in GCC Clause 13

Part IV: Turnkey (if any) as per details in General Technical Specification.

Part V: AnnualMaintenance Contract (AMC) as per details in Technical Specification.

Part VI: Required Terms of Delivery and Destination.

a) For Indigenous goods or for imported goods if supplied from India:

At Consignee Site

.

Insurance (local transportation and storage) would be borne by the Supplier from warehouse to the consignee site for a period including 3 months beyond date of delivery.

b) For Imported goods directly from abroad:

The foreign tenderers are required to quote their rates on DAPat Consignee site basisgivingbreakup of the price as per the Proforma prescribed in the Price Schedule.

The shipping arrangements shall be made in accordance with the instruction of Ministry of Shipping & Transport, New Delhi, India as detailed in Section XXII.

Insurance shall be borne by the supplier.

Insurance (local transportation and storage) would be extended and borne by the Supplier from ware house to the consignee site for a period including 3 months beyond date of delivery.

Destination/Consignee details are given in Section XX

Section – VII
Technical Specifications

Note 1: Tenderer's attention is drawn to GIT clause 17 and GIT sub-clause 10.1 under heading (c) preparation of tenders. The tenderer is to provide the required details, information, confirmations, etc. accordingly failing that it's tender is liable to be ignored.

Note 2: General: Bidders are requested to make sure that they should attach the list of equipments for carrying out routine and preventive maintenance wherever asked for and should make sure that Electrical Safety Analyzer / Tester for Processequipments to periodically check the electrical safety aspects as per BIS Safety Standards IS-13540 which is also equivalent to IEC electrical safety standard IEC-60601 is a part of the equipments. If the Electrical Safety Analyzer/Tester is not available they should provide a commitment to get the equipments checked for electrical safety compliance with Electronic Regional Test Labs / Electronics Test and Development Centers across the country on every preventive maintenance call.

Note 3: OPTIONAL ITEMS: Bidders are requested to quote for all the available options as asked in the bidding document with reasonable pricing. However the pricing for optional items will not be considered for price comparison for ranking purpose. If the firm has not quoted for any optional item (except the items of turnkey - if any) their offer will be treated as TECHNICALLY RESPONSIVE if otherwise meeting the specification.

Refer the following Annexures for the details on IRS&URS's

Annexure I:Installation Requirement Specification (IRS) and Specific Instructions
Annexure II: User RequirementSpecifications

A. Lyophiliser (F1-LYO 01)

B. Lyophiliser (F1-LYO 02)

Note: Specifications packages in separate folder.

Note:

1. **The available clear height inside any of the rooms is 6m. Vendors to check suitability of installing their equipments in this available area and height and revert back with their views.**

   If no views are received from any vendors before or during the pre-bid meeting, it is assumed that the vendor is confident of installing their equipments with-in the area and height available. No further claims shall be entertained.

2. **The extent of automation and optional additional features may vary during the pre-bid discussion.**

3. **The quantity of equipment mentioned in the list may vary during ordering.**

GENERAL TECHNICAL SPECIFICATIONS

GENERAL POINTS:

1. Warranty:

a) Oneyear Comprehensive Warranty as per Conditions of Contract of the TE document for complete equipment and Turnkey (if any) Work from the date of satisfactory installation, commissioning, trial run & handing over of equipment to CONSIGNEE.
b) 98% up time Warranty of complete equipment with extension of Warranty period by double the downtime period on 24 (hrs) X 7 (days) X 365 (days) basis.
c) All software updates should be provided free of cost during Warranty period.

2. After Sales Service:

After sales service centre should be available at the city of CONSIGNEE on 24 (hrs) X 7 (days) X 365 (days) basis. Complaints should be attended properly, maximum within 48 hrs. The service should be provided by Tenderer/Indian Agent. Undertaking by the Principals/ Manufacturer/agent that the spares for the equipment shall be available for at least 10 years from the date of supply. However if the manufacturer/agent does not have the service centres in India will have to set up the same within 45 days after award of the contract.

3. Training:

On Site training to operators/ Technicians/ staff is to be provided by Principal/ Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the consignee.

4. Annual Maintenance Contract (AMC) of subject equipment with Turnkey (if any):

a) The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual of the manufacturer, labour s, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any). The supplier shall visit theconsignee site as recommended in the manufacturer's technical/ service /operational manual, but at least once in threemonths during the AMC period. However incase of break down, the vendor shall attend to the problem within 48 hours from the intimation from the purchaser.
b) The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.
c) Cost of AMC will be added for Ranking/Evaluation purpose.
d) The payment of AMC will be made on six monthly basis, after satisfactory completion of said period, duly certified by end user .
e) There will be 98% uptime warranty during AMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend AMC period by double the downtime period.
f) During AMC period, the supplier is required to visit at each consignee's site at least once in 3months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.
g) All software updates should be provided free of cost during AMC.
h) Failure of the above [4. e) to 4. g)] by the supplier, may lead to the forfeiture of the Bank Guarantee for AMC.
i) The payment of AMC will be made as stipulated in GCC Clause 21.

j) The cost of any spares required during the preventive maintenance/ break down maintenance in the AMC period will be paid extra at actual by the purchaser.

Turnkey (if any):

(i) The Tenderer shall examine the existing site where the equipment is to be installed.

(ii) ***Turnkey (if any) comprises of Supply, Installation, Commissioning and Validation ofLyophilizer***

(iii) Tenderers to quote prices indicating break-up of prices of the Machine.

(iv) The Turnkey costs (if any) may be quoted(Inclusive of all taxes /duties) in Indian Rupee will be added for Ranking Purpose.

Section – VIII
Quality Control Requirements (for each schedule)

(Proforma for equipment and quality control employed by the manufacturer(s)Tender Reference No.

Date of opening
Time
Name and address of the Tenderer:

Note: All the following details shall relate to the manufacturer(s) for the goods quoted for.

01 Name of the manufacturer

a. Full postal address
b. Full address of the premises
c. Email ID
d. Telephone number
e. Fax number

02 Plant and machinery details

03 Manufacturing process details

04 Monthly (single shift) production capacity of goods quoted for

a. normal
b. maximum

05 Total annual turn-over (value in Rupees) for the last three calendar years excluding the year of tender opening:

06 Quality control arrangement details

a. for incoming materials and bought-out components
b. for process control
c. for final product evaluation

07 Test certificate held

a . type test
b . BIS/ISO certification
c . any other

08 Details of staff

a. technical
b skilled
c unskilled

09 Please furnish documentation details with clarifications etc as asked for at the end of the equipment specification.

Signature and seal of the Tenderer

Section – IX
Qualification Criteria

1. "The tenderer:

   Has to be a manufacturer of the tendered equipment.

   OR

   Has to be an authorised Indian representative of the equipment manufacturer of the tendered equipment."

2. In case the manufacturer of the tendered equipment is of foreign origin, the manufacturer should have a Permanent Establishment or Authorised Representative in India for carrying out the activities of Clearing, Forwarding, Transportation, Installation, Commissioning, Qualification, Training, Warranty.

3. The Tenderer should have successfully supplied, installed & commissioned at-least two lyophilizers : One lyophilizer of 10 m^2 capacity (i.e. capacity equivalent to 40,000 vials/batch of 2 R vials (ISO specification)) and One lyophilizer of 20 m^2 capacity(i.e. capacity equivalent to 80,000 vials/batch of 4R vials (ISO specification)), having CE certification in the last seven years prior to the date of Tender Opening, in the field of human vaccine formulation. (installation certificate or Completion certificate for the lyophilizers supplied to be attached).

4. With reference to point no. 3, their Clients list must include at-least two facilities approved from national regulatory body (NRA) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU).

5. The average annual turnover of the tenderer must be minimum INR.935.00 Lakh (or equivalent in Foreign Currency) during the last three financial year (2011-12, 2012-13 and 2013-14).

6. Net worth of the Tenderer should be positive during the last three financial years (2011-12, 2012-13 and 2013-14).

7. The manufacturer and authorized Indian agent should jointly have atleast three years of experience in installing and commissioning of lyophilizer in India with record of proof. (Record of proof: Agreement between the two parties to install and commission the lyophilizer in India). The detailed list of service/maintenance team in India with their experience to be enclosed along with the bid document.

Note:

- In support of above the Tenderer shall furnish the details in the below tables.
- The manufacturer as well as the Tenderer/ Indian Agent shall furnish Satisfactory Performance cum Installation Certificate/purchase orders/bill of entry in respect of above, duly translated in English and duly notarized in the country of origin, along with the tender.
- The Tenderer shall furnish a brief write-up, packed with adequate data explaining and establishing his available capacity/capability (both technical and financial) to perform the Contract (if awarded) within the stipulated time period, after meeting all its current/present commitments. The Tenderer shall also furnish details of Equipment and Quality Control in the enclosed Section below.
- The Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening certified by a Chartered Accountant should be submitted as part of the tender
- Notwithstanding anything stated above, the Purchaser reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily before deciding on award of Contract, should circumstances warrant such an assessment in the overall interest of the Purchaser. The Purchaser reserves the right to ask for a free demonstration of the quoted equipment to similar/identical specification at a pre determined place acceptable to the purchaser for determining technical responsiveness, before the opening of the Price Bid.
- The Purchaser also reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily by inspecting their facility. Such assessment shall be done before opening of the Price Bid and the assessment report shall form part of TCTR.

PROFORMA:

Section (A).	General information:	
1	Name of Company	
2	Registration No.	
3	Number of Years in Operation	
4	Registered address	
5	Operating address	
6	Telephone No	
7	Telefax	
8	Email Address	
9	SERVICE TAX No.	
10	PAN No.	
11	TIN No.	

Section (B).	FINANCE		
1	**Name & Address of Banks and Branches used :**		
1.1			
1.2			
1.3	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
2	What is your average annual invoiced sales value (based on past previous 5 year's records) for each of the type of equipments under consideration.		
	Equipment Name: ---------- (If more then one equipment, enclose the same separately)		
2.1	Year 1	_____ (Value in Lakhs)	
	Year 2	_____ (Value in Lakhs)	
	Year 3	_____ (Value in Lakhs)	
	Year 4	_____ (Value in Lakhs)	
	Year 5	_____ (Value in Lakhs)	
2.2	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
3	Annual Turnover of the Firm/ company:		
3.1	2013 – 2014:	_____ (Value in Lakhs)	
	2012 – 2013:	_____ (Value in Lakhs)	
	2011 – 2012:	_____ (Value in Lakhs)	
3.2	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
4	Bidders are to submit copy of valid current Income Tax Return submitted, Sales Tax Registration failing which their offer may be liable to be rejected.		❑ Yes ❑ no

Section (C)	EXPERIENCE:					
1	**Past Project Experience:** 1. The Tenderer should have supplied,installed & commissioned successfully at-least two lyophilizers: One lyophilizer of 10 m^2 capacity (i.e. capacity equivalent to 40,000 vials/batch of 2R vials) and One lyophilizer of 20 m^2 capacity(i.e. capacity equivalent to 80,000 vials/batch of 4R vials), having CE certification in the last seven years from the date of Tender Opening in the field of vaccine formulation. (Purchase order or installation certificate or Completion certificate or bill of entry of the lyophilizers to be attached). 2. Their Client's list must include at-least two facilities approved from national regulatory body (NRA) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU).					
Sl. No.	**Year awarded**	**Project Name**	**Equipments Supplied**	**CONTRACT VALUE (INR)**	**CLIENT NAME & REFERENCE (Contact details)**	**Facility Approved by: (Name of approving agency)**
	Documentary evidence of work completion certificate duly signed & stamped must be enclosed including the evidence of the facility having approved by regulatory agencies.					❑ Yes ❑ no
2	**Details of Ongoing project:**					
Sl. No.	**Year awarded**	**Project Name**	**Equipments Supplied**	**CONTRACT VALUE (INR)**	**CLIENT NAME & REFERENCE (Contact details)**	**Remarks**
	Documentary evidence of the same to be enclosed					❑ Yes ❑ no

Section (D).	QUALITY

1	**ISO CERTIFICATION**	
	Is your company ISO certified, if so mention the certification number and enclose the photocopy of the certificate: ISO_____ ISO_____ ISO_____	❑ Yes ❑ no
2	Enclose the company Quality policy	❑ Yes ❑ no
3	The equipment supplied should comply with the following guidelines / standards. Note: Subject to the kind of equipment supplied.	❑ Yes ❑ no
3.1	**cGMP-Regulations**	❑ Yes ❑ no
3.1.1	EU-GMP-Guideline Part 1, Annexes 1, 11& 15	❑ Yes ❑ no
3.1.2	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs: General.	❑ Yes ❑ no
3.1.3	21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals.	❑ Yes ❑ no
3.1.4	Schedule “M” GMP	❑ Yes ❑ no
3.1.5	21 CFR Part 11: Electronic Records; Electronic Signatures	❑ Yes ❑ no
3.2	**FDA Guidance for Industry**	❑ Yes ❑ no
3.2.1	Sterile Drug Products Produced by Aseptic Processing	❑ Yes ❑ no
3.3	**GAMP**	❑ Yes ❑ no
3.3.1	The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 5.	❑ Yes ❑ no
3.4	**CE Conformity**	
3.4.1	A CE declaration of conformity must be available. The CE identification must comply with the current EC commission.	❑ Yes ❑ no
3.5	**Operating safety act**	

3.5.1	The requirements of the Operating safety act must be observed.	❑ Yes ❑ no
3.6	**ISO 14664**	
3.6.1	Clean rooms and Associated Controlled Environment	❑ Yes ❑ no

Section (E). ATTACHMENTS		
S. No.	**Please provide the following documents in your submissions:**	**Enclosed**
1	Company Brochure / Literature	❑ Yes ❑ no
2	Product profile	❑ Yes ❑ no
3	Technical Details of equipments	❑ Yes ❑ no
4	Name & Address of Banks and Branches used : (duly signed & stamped)	❑ Yes ❑ no
5	**Annual turnover for the following years**	
	2013 – 2014: Balance sheet (duly signed & stamped)	❑ Yes ❑ no
	2012 – 2013: Balance sheet (duly signed & stamped)	❑ Yes ❑ no
	2011 – 2012: Balance sheet (duly signed & stamped)	❑ Yes ❑ no
6	current Income Tax Return	❑ Yes ❑ no
	Sales Tax Registration	❑ Yes ❑ no
7	Past project experience: Completion certificate:	❑ Yes ❑ no
8	Ongoing project details.	❑ Yes ❑ no
9	ISO Certificates	❑ Yes ❑ no
10	Company policies	❑ Yes ❑ no
11	Equipment list / scope of supply	❑ Yes ❑ no

Signature and seal of the Tenderer

**** The documentary proof will be a certificate (enclosed) from the consignee/end user/purchaser with cross-reference of order no. and date in the certificate duly notarised certification authenticating the correctness of the information furnished. If at any time, information furnished is proved to be false or incorrect, the earnest money and or performance security furnished will be forfeited .such certificates from a third party or middleman other than actual end user/purchaser will not be accepted.**

FORMAT OF PERFORMANCE CERTIFICATE

To whom it may concern

Date. _____

Certified that M/s ----------(name & address of the manufacturer) supplied us ----------Nos (indicate quantity) of equipment, ----------(indicate name of the equipment) against our order no ----------dt ----------(please indicate order no & date as figuring in the performance statement). The equipment was installed, commissioned & handed over to us on ----------(indicate date) & since then the equipment has been working to our entire satisfaction.

Section – X
TENDER FORM

Date_____
To

_____

HLL Biotech Limited, Chennai

Ref. Your TE document No. _____dated _____
We, the undersigned have examined the above mentioned TE document, including amendment/corrigendum No. _____, dated _____ (*if any*), the receipt of which is hereby confirmed. We now offer to supply and deliver_____ *(Description of goods and services)* in conformity with your above referred document for the sum of _____ (total tender amount in figures and words), as shown in the price schedule(s), attached herewith and made part of this tender.

If our tender is accepted, we undertake to supply the goods and perform the services as mentioned above, in accordance with the delivery schedule specified in the List of Requirements.

We further confirm that, if our tender is accepted, we shall provide you with a performance security of required amount in an acceptable form in terms of GCC clause 5, read with modification, if any, in Section - V – "Special Conditions of Contract", for due performance of the contract.

We agree to keep our tender valid for acceptance as required in the GIT clause 19, read with modification, if any in Section - III – "Special Instructions to Tenderers" or for subsequently extended period, if any, agreed to by us. We also accordingly confirm to abide by this tender up to the aforesaid period and this tender may be accepted any time before the expiry of the aforesaid period. We further confirm that, until a formal contract is executed, this tender read with your written acceptance thereof within the aforesaid period shall constitute a binding contract between us.

We further understand that you are not bound to accept the lowest or any tender you may receive against your above-referred tender enquiry.

We confirm that we do not stand deregistered/banned/blacklisted by any Govt. Authorities.

We confirm that we fully agree to the terms and conditions specified in above mentioned TE document, including amendment/ corrigendum if any

---

(Signature with date)

(Name and designation) Duly authorised to sign tender for and on behalf of

SECTION – XI A PRICE SCHEDULE
i) PRICE SCHEDULE FOR DOMESTIC GOODS OR GOODS OF FOREIGN ORIGIN LOCATED WITHIN INDIA

1	2	3	4	5						6
				Price per unit (Rs.)						
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Ex - factory/ Ex -warehouse /Ex showroom /Off - the shelf (a)	Excise Duty (if any) [%age & value] (b)	CST/ VAT(if any) [%age & value] (c)	Packing and Forwarding charges (d)	Incidental Services (including Installation & Commissioning, Supervision, Demonstration ,Training, Documentaion and Qualification) at the Consignee's site e)	Unit Price (at Consignee Site) basis (f) =a+b+c+d+e	Total Price (at Consignee Site) basis (Rs.) 4 x 5(f)

NB: Unit price shall be written in figures and words

Total Tender price in Rupees: _____

In words:

_____

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for AMC after warranty shall be quoted separately as per Section – XI – Price Schedule C

Name_____

Business Address_____

Place: _____ **Signature of Tenderer** _____

Date: _____ **Seal of the Tenderer**_____

SECTION – XI B PRICE SCHEDULE
i) PRICE SCHEDULE FOR GOODS TO BE IMPORTED FROM ABROAD

1	2	3	4	5										6
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Price per unit (Currency)										Total price on DAP basis at consignee's site 4X 5 (j)
				Gross FOB price at sea / air port of Lading (inclusive of Agency (commission)	Amount and percentage of Agency Commission **	Net FOB (excluding Agency Commission) (a-b)	Insurance & Freight	Net CIP Port of destination by Air/sea ((c+d)	Customs duty % & HS Code	Customs Clearance & Handling Charges **	Loading / unloading / inland transportation & incidental cost till consignee's site **	Installation, commissioning, supervision, Demonstration,training Documentaion and Qualification at the consignee's site **	Unit price on DAP basis at consignee's site (a+df+g+h+i)	
				(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)

** To be paid in Indian Currency (Rs.)
Total DAP at Consignee site price
in_____

And in words:
_____

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for Annual Maintenance Contract (AMC) after warranty shall be quoted separately as per Section – XI – Price Schedule C
3. The Tenderer will be fully responsible for the safe arrival of the goods at Consignee Site
4. The quoted price should be bidder's best lowest rate supported with original proforma invoice from the foreign manufacturers Indian Agent to be paid in Indian Currency.

Signature of Tenderer_____
Name_____
Business Address_____
Place: _____
Signature of Tenderer_____
Date: _____
Seal of the Tender_____

SECTION – XIC PRICE SCHEDULE
PRICE SCHEDULE FOR ANNUAL MAINTENANCE CONTRACT AFTER WARRANTY PERIOD

1	2	3	4		5
Schedule No.	BRIEF DESCRIPTION OF GOODS	QUANTITY. (Nos.)	Annual Maintenance Contract Cost for Each Unit year wise*.		Total Annual Comprehensive Maintenance Contract Cost for 2 Years [3 x (4A+4B)]
			1st	2nd	
			A	B	

*** After completion of Warranty period**

NOTE:-

1. In case of discrepancy between unit price and total prices, THE UNIT PRICE shall prevail.
2. The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual, labour and spares, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any).
3. The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. **The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.**
4. Cost of AMC will be added for Ranking/Evaluation purpose.
5. The payment of AMC will be made as per clause GCC clause 21.1 (D).
6. The uptime warranty will be 98 % on 24 (hrs) X 7 (days) X 365 (days) basis or as stated in Technical Specification of the TE document.
7. All software updates should be provided free of cost during AMC period.
8. The stipulations in Technical Specification will supersede above provisions
9. The supplier shall keep sufficient stock of spares required during Annual Maintenance Contract period. In case the spares are required to be imported, it would be the responsibility of the supplier to import and get them custom cleared and pay all necessary duties.
10. Agency commission may be shown in separate column in price schedule.
11. The cost of spares required during the preventive maintenance/ breakdown maintenance during the AMC shall be paid extra at actual by the purchaser.

Name _____

Business Address _____

Place: _____ **Signature of Tenderer** _____

Date: _____ **Seal of the Tenderer** _____

SECTION – XI D PRICE SCHEDULE
PRICE SCHEDULE FOR TURNKEY (if any)

Schedule No.	BRIEF TURNKEY (IF ANY) DESCRIPTION OF GOODS	Turnkey (if any) price

Note: -

1. The cost of Turnkey (if any) as per Technical Specification (Section VII) may be quoted on lump sum inclusive of all taxes & duties. Cost of Turnkey (if any) will be added for Ranking/Evaluation purpose.
2. The payment of Turnkey (if any) will be madeas per clause GCC clause 21.1 (c).
3. The stipulations in Technical Specification will supersede above provisions

Name _____

Business Address _____

Place: _____ **Signature of Tenderer** _____

Date: _____ **Seal of the Tenderer** _____

SECTION – XII
QUESTIONNAIRE

Fill up the Section XIX – Check List for Tenderers and enclose with the Tender

1. The tenderer should furnish specific answers to all the questions/issues mentioned in the Checklist. In case a question/issue does not apply to a tenderer, the same should be answered with the remark “not applicable”
2. Wherever necessary and applicable, the tenderer shall enclose certified copy as documentary proof/ evidence to substantiate the corresponding statement.
3. In case a tenderer furnishes a wrong or evasive answer against any of the question/issues mentioned in the Checklist, its tender will be liable to be ignored.

SECTION – XIII
BANK GUARANTEE FORM FOR EMD

Whereas _____ (hereinafter called the "Tenderer") has submitted its quotation dated _____ for the supply of _____ (hereinafter called the "tender") against the purchaser's tender enquiry No. _____ Know all persons by these presents that we _____ of _____ (Hereinafter called the "Bank") having our registered office at _____ are bound unto _____ (hereinafter called the "Purchaser) in the sum of _____ for which payment will and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this _____ day of _____ 20____. The conditions of this obligation are:

(1) If the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.

(2) If the Tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity:-

a) fails or refuses to furnish the performance security for the due performance of the contract.
or
b) fails or refuses to accept/execute the contract.
or
c) if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged

We undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition(s).

This guarantee will remain in force for a period of forty-five days after the period of tender validity and any demand in respect thereof should reach the Bank not later than the above date.

(Signature of the authorised officer of the Bank)

Name and designation of the officer

Seal, name & address of the Bank and address of the Branch

SECTION – XIV
MANUFACTURER'S AUTHORISATION FORM

To

HLL Biotech Limited, Chennai

Dear Sirs,

Ref. Your TE document No _____, dated _____

We, _____ who are proven and reputable manufacturers of_____(*name and description of the goods offered in the tender*) having factories at_____, hereby authorise Messrs_____(*name and address of the agent*) to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs. _____ (*name and address of the above agent*) is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, AMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

Yours faithfully,

[*Signature with date, name and designation*]
for and on behalf of Messrs_____

[*Name & address of the manufacturers*]

Note:

1. *This letter of authorisation should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.*
2. *Original letter may be sent.*

SECTION – XV (A)

BANK GUARANTEE FORM FOR ADVANCE BANK GUARANTEE

Ref..... Date.....

Bank Guarantee No....

To

HLL Biotech Ltd.,
Module 013-015,
Ticel Biopark Campus,
CSIR Road, Taramani,
Chennai – 600 113.

Dear Sirs,

In consideration of the HLL Biotech Ltd., hereinafter referred to as 'HBL', which expression shall unless repugnant to the context or meaning thereof include its successors, executors, administrators and assigns, having awarded to M/s._____ having itsregistered office at _____
hereinafter referred as the 'Supplier', which expression shall unless repugnant to the context or meaning thereof, include its successors, Administrators, executors and assigns, a contract hereinafter referred to as the 'Order' for _____referred to as the 'Supply and Services' on terms and conditions set out, inter-alia in the HBL's Order No. _____ dated _____valued _____at (in words & figures) and as the HBL having agreed to make a payment against the above ORDER, to the Supplier amounting to Rs. _____(in words & figures) as an advance against Bank Guarantee to be furnished by the Supplier, the said advance to be adjusted against the supply and servicesto be performed by the Supplier, we _____ hereinafter referred to as the `Bank' which expressions shall, unless repugnant to the context or meaning thereof, include its successors, administrators, executors and assigns **having our office at** _____**do hereby undertake to give the irrevocable and unconditional guarantee and** do hereby undertake to pay the HBL on first demand without any demur, **reservation, contest recourse and protest and without reference to the Supplier** any and all monies payable by the Supplier by reason of any breach by the said Supplier of any of the terms and conditions of the said order to the extent of Rs. _____ (in words & figures) till the said advance is adjusted as aforesaid at any time upto _____.We agree that the guarantee herein contained shall continue to be enforceable till the sum due to the HBL on account of the said advance is adjusted/recovered in full as aforesaid or till the HBL discharges this guarantee.

The HBL shall have the fullest liberty without affecting in any way the liability of the Bank under this guarantee, from time to time vary the advance or to extend the time for performance of the supply and services by the Supplier. The Bank shall not be released from its liability under these presents by any exercise of the HBL of the liberty with reference to the matter aforesaid.
The HBL shall have the fullest liberty, **without reference to Supplier and** without affecting this guarantee to postpone **for any time or** from time to time the exercise of any powers vested in them or of any right which they might have against the Supplier, and to exercise the same at any time in any manner, and either to enforce or to forebear to enforce any **power**, covenants contained or implied in the order between the HBL and the Supplier or any other course or remedy or security available to the HBL and the Bank shall not be released of its obligations under these presents by any exercise by the HBL of its liberty with reference to matters aforesaid or any of them or by reason of any other act or forbearance or other acts of omission or commission on the part of the HBL or any other indulgence shown by the HBL or by any other matter or thing whatsoever which under law would, but for this provision, have the effect of relieving the Bank Guarantee.

The right of HBL to recover the outstanding sum of advance with applicable costs upto Rs._____ from the bank in the manner aforesaid will not be affected or suspended by reason of the fact that any dispute or disputes is or are pending before any officer, tribunal or court and any demand made by HBL on the Bank shall be conclusive and binding.

The Bank further undertakes not to revoke this guarantee during its currency without prior and written consent of the **HBLand further agrees that the guarantee contained shall continue to be enforceable till the HBL discharges this guarantee.**

The Bank also agrees that the HBL shall at its option is entitled to enforce this guarantee against the bank as principal debtors, in first instance, notwithstanding any other security or guarantee that **HBL** may have in relation to the Supplier's liabilities of the said advance.

Notwithstanding anything contained herein above, our liability under this guarantee is restricted to as Rs. _____(in words & figures) and it will remain in force upto and including (date of completion of supply and services) and shall be extended from time to time for such periods as may be advised by M/s…… on whose behalf this guarantee has been given.

Therefore, we hereby affirm that we are guarantors and responsible to you on behalf of the Supplier upto a total amount of _____(amount of guarantees in words and figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the purchase order and without caveat or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or show grounds or reasons for your demand or the sum specified therein.

This Guarantee is valid until _____ day _____.

We have power to issue this guarantee in your favour under Memorandum and Articles of Association and the undersigned has full power to do under the Power of Attorney / Resolution of Board of Directors dated.....granted to him by the Bank.

Dated.....this.....day of.....2013

Signed by
Place:

(Person duly authorised by Bank)
Witness :

SECTION – XV (B)

BANK GUARANTEE FORM FOR PERFORMANCE SECURITY/ AMC SECURITY

To

HLL Biotech Ltd.,
Module 013-015,
Ticel Biopark Campus,
CSIR Road, Taramani,
Chennai – 600 113.

1. In consideration of HLL Biotech Limited (hereinafter called "HBL") having agreed under the terms and conditions of Order No…….. dated……. made between …… (here in after called "the said contractor(s)") for the …….. work (herein after called "the said agreement") for compliance of his obligation in accordance with the terms and conditions in the said agreement.

We …….. (indicate the name of the Bank) (herein after referred to as "as Bank) hereby undertake to pay to the HBL and amount not exceeding Rs….. (Rupees…….. only) on demand by HBL.

2. We …….. (Indicate the name of the Bank) do hereby undertake to pay the amount due and payable under this Guarantee without any demure, merely on a demand from HBL stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). any such demand made on the Bank shall be conclusive as regards the amount due and payable by the bank under this Guarantee. However, our liability under this guarantee shall be restricted to an amount not exceeding Rs…… (Rupees…… only).

3. We undertake to pay to HBL any money so demanded notwithstanding any dispute or disputes raised by the contractor (s) in any suit or proceeding pending before any court or Tribunal relating thereto our liability under this present being absolute and unequivocal.

The payment made by us under this guarantee shall be valid discharge of our liability for payment to there-under and the contractor(s) shall have no claim against us making such payment.

4. We …….. (Indicate the name of Bank) further agree that the guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement and that it shall continue to be enforceable till all the dues of HBL under or by virtue of the said agreement have been fully paid and its claims satisfied or discharged or till Engineer-in-charge on behalf of HBL Certified that the terms and conditions of the said Agreement have been fully and properly carried out by the said contractor(s) accordingly discharges this guarantee.

5. We……. (Indicate the name of Bank) further agree with HBL that HBL shall have the fullest liberty without our consent and without affecting any manner our obligations hereunder to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time or to postpone for any of the powers exercisable by HBL against the said contractor(s) and to forebear or enforce any of the terms and conditions relating to the said agreement we shall not be relieved from our liability by reasons of any such variation or extension being granted to the said contractor(s) or for any forbearance act of omission on that part of the HBL or any indulgence by HBL to the said contract(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effected or so relieving us.

6. The guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).

7. We…… (indicate the name of Bank) lastly undertake not to revoke this guarantee except with the previous consent of HBL in writing.

8. This guarantee shall be valid up to …….. unless extended on demand by HBL. Notwithstanding anything mentioned above our liability against this Guarantee is restricted to Rs……. (Rupees……only) and unless a claim in writing is lodged with us within six months of the date of expiry or the extended date of expiry of this guarantee, all our liabilities under the Guarantee shall stand discharged.

Dated the …….. day of 20….

For ……
(Indicate the name of Bank)

SECTION – XVI
CONTRACT FORM - A

CONTRACT FORM FOR SUPPLY, INSTALLATION, COMMISSIONING, HANDING OVER, TRIAL RUN, TRAINING OF OPERATORS & WARRANTY OF GOODS

HLL Biotech Limited

Contract No_____ dated_____

This is in continuation to this office's Notification of Award No_____ dated _____

1. Name & address of the Supplier: _____
2. Purchaser's TE document No_____ dated_____ and subsequent Amendment No_____, dated_____ (if any), issued by the purchaser
3. Supplier's Tender No_____ dated_____ and subsequent communication(s) No_____ dated _____ (if any), exchanged between the supplier and the purchaser in connection with this tender.
4. In addition to this Contract Form, the following documents etc, which are included in the documents mentioned under paragraphs 2 and 3 above, shall also be deemed to form and be read and construed as integral part of this contract:

   (i) General Conditions of Contract;
   (ii) Special Conditions of Contract;
   (iii) List of Requirements;
   (iv) Technical Specifications;
   (v) Quality Control Requirements;
   (vi) Tender Form furnished by the supplier;
   (vii) Price Schedule(s) furnished by the supplier in its tender;
   (viii) Manufacturers' Authorisation Form (if applicable for this tender);
   (ix) Purchaser's Notification of Award

   Note: The words and expressions used in this contract shall have the same meanings as are respectively assigned to them in the conditions of contract referred to above. Further, the definitions and abbreviations incorporated under clause 1 of Section II – 'General Instructions to Tenderers' of the Purchaser's TE document shall also apply to this contract.

5. Some terms, conditions, stipulations etc. out of the above-referred documents are reproduced below for ready reference:

   (i) Brief particulars of the goods and services which shall be supplied/ provided by the supplier are as under:

Schedule No.	Brief description of goods/services	Accounting unit	Quantity to be supplied	Unit Price	Total price	Terms of delivery

Any other additional services (if applicable) and cost thereof: _____

Total value (in figure) _____ (In words) _____

1. Delivery schedule

   (i) Details of Performance Security

   (ii) Quality Control

   (a) Mode(s), stage(s) and place(s) of conducting inspections and tests.
   (b) Designation and address of purchaser's inspecting officer

   (iii) Destination and despatch instructions

   (iv) Consignee, including port consignee, if any

2. Warranty clause
3. Payment terms
4. Paying authority

_____

(Signature, name and address of CONSIGNEE)

For and on behalf of_____

Received and accepted this contract

(Signature, name and address of the supplier's executive duly authorised to sign on behalf of the supplier)
For and on behalf of _____
(Name and address of the supplier)

(Seal of the supplier)

Date: _____

Place: _____

SECTION – XVI
CONTRACT FORM – B
CONTRACT FORM FOR ANNUAL MAINTENANCE CONTRACT

Annual CM Contract No._____ **dated**_____

Between

_____

_____

CONSIGNEE
And

_____

_____

(Name & Address of the Supplier)

Ref: **Contract No**_____ **dated**_____ **(Contract No. & date of Contract for supply, installation, commissioning, handing over, Trial run, Training of operators & warranty of goods)**

In continuation to the above referred contract

2. The Contract of Annual Comprehensive Maintenance is hereby concluded as under: -

1	2	3	4		5
Schedule No.	**BRIEF DESCRIPTION OF GOODS**	**QUANTITY. (Nos.)**	**Annual Maintenance Contract Cost for Each Unit year wise*.**		**Total Annual Maintenance Contract Cost for 2Years [3 x (4A+4B)]**
			1st	**2nd**	
			A	**B**	

Total value (in figure) _____ (In words) _____

b) The AMC commence from the date of expiry of all obligations under Warranty i.e. from_____ (date of expiry of Warranty) and will expire on _____ (date of expiry of AMC)

c) The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance, labour and spares, after satisfactory completion of Warranty period may be quoted for next 2years as contained in the above referred contract on yearly basis for complete equipment and Turnkey (if any).

d) There will be 98% uptime warranty during AMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend AMC period by double the downtime period.

e) During AMC period, the supplier shall visit at each consignee's site for preventive maintenance including testing and calibration as per the manufacturer's service/ technical/ operational manual. The supplier shall visit each consignee site as recommended in the manufacturer's manual, but at least once in 3 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.

f) All software updates should be provided free of cost during AMC.

g) **Payment terms:**The payment of AMC will be made against the bills raised to the consignee by the supplier on six monthly basis after satisfactory completion of said period, duly certified by the HOD concerned. The payment will be made in Indian Rupees.

_____ (name of the consignee)

_____

(Signature, name and address of Consignee)

For and on behalf of_____

Received and accepted this contract

(Signature, name and address of the supplier's executive
duly authorised to sign on behalf of the supplier)

For and on behalf of _____
(Name and address of the supplier)

(Seal of the supplier)

Date: _____

Place: _____

SECTION – XVII
PROFORMA OF CONSIGNEE RECEIPT CERTIFICATE
(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) Contract No. & date :_____

2) Supplier's Name :_____

3) Consignee's Name & Address with telephone No. & Fax No. : _____

4) Name of the item supplied :_____

5) Quantity Supplied :_____

6) Date of Receipt by the Consignee :_____

7) Name and designation of Authorized Representative of Consignee :_____

8) Signature of Authorized Representative of Consignee with date :_____

9) Seal of the Consignee :_____

SECTION – XVIII
Proforma of Final Acceptance Certificate by the Consignee

No_____

Date_____

To

M/s _____
_____
_____

Subject: Certificate of commissioning of equipment/plant.

This is to certify that the equipment(s)/plant(s) as detailed below has/have been received in good conditions along with all the standard and special accessories and a set of spares (subject to remarks in Para no.02) in accordance with the contract/technical specifications. The same has been installed and commissioned.

(a) Contract No_____ dated_____

(b) Description of the equipment(s)/plants:_____

(c) Equipment(s)/ plant(s) nos.:_____

(d)Quantity:_____

(e) Bill of Loading/Air Way Bill/Railway Receipt/ Goods Consignment Note no_____ dated _____

(f) Name of the vessel/Transporter:_____

(g) Name of the Consignee:_____

(h) Date of commissioning and proving test:_____

Details of accessories/spares not yet supplied and recoveries to be made on that account.

Sl. No.	Description of Item	Quantity	Amount to be recovered

The proving test has been done to our entire satisfaction and operators have been trained to operate the equipment(s)/plant(s).

The supplier has fulfilled its contractual obligations satisfactorily ## or

The supplier has failed to fulfill its contractual obligations with regard to the following:

- He has not adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specifications'.
- He has not supervised the commissioning of the equipment(s)/plant(s)in time, i.e. within the period specified in the contract from date of intimation by the Purchaser/Consignee in respect of the installation of the equipment(s)/plant(s).
- The supplier as specified in the contract has not done training of personnel.

The extent of delay for each of the activities to be performed by the supplier in terms of the contract is:

The amount of recovery on account of non-supply of accessories and spares is given under Para no.02.

The amount of recovery on account of failure of the supplier to meet his contractual obligations is_____ (here indicate the amount).

Signature
Name
Designation with stamp

Explanatory notes for filling up the certificate:

He has adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specification'.

He has supervised the commissioning of the equipment(s)/plant(s) in time, i.e. within the time specified in the contract from date of intimation by the Purchaser/Consignee in respect of the installation of the equipment(s)/plant(s).

Training of personnel has been done by the supplier as specified in the contract
In the event of documents/drawings having not been supplied or installation and commissioning of the equipment(s)/plant(s) having been delayed on account of the supplier, the extent of delay should always be mentioned in clear terms.

SECTION – XIX
CHECKLIST

NAME OF TENDERER:

NAME OF MANUFACTURER:

Sl No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
1. a.	Have you enclosed EMD of required amount for the quoted schedules?			
b.	In case EMD is furnished in the form of Bank Guarantee, has it been furnished as per Section XIII?			
c.	In case Bank Guarantee is furnished, have you kept its validity of 165 days from Technical Bid Opening date as per clause 18 of GIT?			
2. a.	Have you enclosed duly filled Tender Form as per format in Section X?			
b.	Have you enclosed Power of Attorney in favour of the signatory?			
3.	Are you a SSI unit, if yes have you enclosed certificate of registration issued by Directorate of Industries/NSIC			
4. a.	Have you enclosed clause-by-clause technical compliance statement for the quoted goods vis-à-vis the Technical specifications?			
b.	In case of Technical deviations in the compliance statement, have you identified and marked the deviations?			
5. a.	Have you submitted satisfactory performance certificate as per the Proforma for performance statement in Sec. IX of TE document in respect of all orders?			
b.	Have you submitted copy of the order(s) and end user certificate?			
6.	Have you submitted manufacturer's authorization as per Section XIV?			
7.	Have you submitted prices of goods, turnkey (if any), AMC etc. in the Price Schedule as per Section XI?			
8.	Have you kept validity of 120 days from the Technical bid Opening date as per the TE document?			
9. a.	In case of Indian Tenderer, have you furnished Income Tax Account No. as allotted by the Income Tax Department of Government of India?			

Sl No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
b.	In case of Foreign Tenderer, have you furnished Income Tax Account No. of your Indian Agent as allotted by the Income Tax Department of Government of India?			
10.	Have you intimated the name and full address of your Banker (s) along with your Account Number			
11.	Have you fully accepted payment terms as per TE document?			
12.	Have you fully accepted delivery period as per TE document?			
13.	Have you submitted the certificate of origin			
14.	Have you accepted the warranty as per TE document?			
15.	Have you accepted terms and conditions of TE document?			
16.	Have you furnished documents establishing your eligibility & qualification criteria as per TE documents?			
17	Have you furnished Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening?			
18	Have you signed and sealed the Integrity Pact as per section XXI of the tender			
19	Have you enclosed the DD/Bankers cheque for the tender fee?			

N.B.

1. All pages of the Tender should be page numbered and indexed.
2. The Tenderer may go through the checklist and ensure that all the documents/confirmations listed above are enclosed in the tender and no column is left blank. If any column is not applicable, it may be filled up as NA.
3. It is the responsibility of tendered to go through the TE document to ensure furnishing all required documents in addition to above, if any.

(Signature with date)

(Full name, designation & address of the person duly authorised sign on behalf of the Tenderer)
For and on behalf of

(Name, address and stamp of the tendering firm)

Section – XX

Consignee

All Goods shall be delivered at

"INTEGRATED VACCINES COMPLEX, CHENGALPATTU- 603001, TAMILNADU, INDIA"

SECTION – XXI

To be signed by the bidder and same signatory competent/authorized to sign the relevant contract of behalf of HLL Biotech Limited

INTEGRITY AGREEMENT

This Integrity Agreement is made at …… on this ……. Day of……..20……

BETWEEN

President of India represented throughCHIEF EXECUTIVE OFFICER, HLL Biotech Limited (Hereinafter referred as the "Principal/Owner", which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns.

AND

……
through ……..(Hereinafter referred to as the **"Bidder/Contractor**" and which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns).

Preamble

WHEREAS the Principal / owner has floated the Tender (NIT No……..)
(hereinafter referred to as "**Tender/Bid**") and intends to award, under laid down organizational procedure, contract for ……
Hereinafter referred to as the **"Contract"**

AND WHEREAS the Principal /Owner values full compliance with all relevant laws of the land, rules, regulations, economic use of resources and of fairness/transparency in its relation with its Bidder(s) and Contractor(s).

AND WHEREAS to meet the purpose aforesaid both the parties have agreed to enter into this Integrity Agreement (hereinafter referred to as **"Integrity Pact**" or **" Pact**"), the terms and conditions of which shall also be read as integral part and parcel of the Tender Bid documents and Contract between the parties. NOW, THEREFORE, in consideration of mutual covenants' contained in this Pact, the parties hereby agree as follows and this Pact witnesses as under:

Article 1: Commitment of the Principal /Owner

1) The Principal /Owner commits itself to take all measures necessary to prevent corruption and to observe the following principles.

   (a) No employee of the Principal/Owner, personally or through any of his/her family members, will in connection with the Tender, or the execution of the Contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.

   (b) The Principal/Owner will, during the Tender process, treat all Bidder(s) with equity and reason. The Principal/owner will, in particular, before and during the Tender process, provide to all Bidder(s) the same information and will not provide to any Bidder(s) confidential / additional information through which the Bidder(s) could obtain an advantage in relation to the Tender process or the Contract execution.

   (c) The Principal /Owner shall Endeavour to exclude from the Tender process any person, whose conduct in the past has been of biased nature.

2) If the Principal/Owner obtains information on the conduct t of any of its employees which is a criminal offence under the Indian Penal code (IPC)/Prevention of Corruption Act, 1988 (PC Act) or is in violation of the principles herein mentioned or if there be a substantive suspicion in this regard, the Principal/Owner will inform the Chief Vigilance Officer and in addition can also in initiate disciplinary actions as per its internal laid down policies and procedures.

Article 2:Commitment of the Bidder(s) / Contractor(s)

1) It is required that each Bidder/Contractor(including their respective officers, employees and agents) adhere to the highest ethical standards, and report to the Government/Department all suspected acts of **fraud or corruption or Coercion or Collusion** of which it has knowledge or becomes aware, during the tendering process and throughout the negotiation or award of a contract.

2) The Bidder(s)/Contractor(s) commit himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the Tender process and during the Contract execution.

   (a) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm, offer, promise or give to any of the Principal/owner's employees involved in the Tender process or execution of the Contract or to any third person any material or other benefit which he/she which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the Tender process or during the execution of the Contract.

   (b) The Bidder(s) will not enter with other Bidder(s) into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certification, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to cartelize in the bidding process.

   (c) The Bidder(s)/Contractor(s) will not commit any offence under the relevant IPC/PC Act. Further the Bidder(s) /Contract(s) will not use improperly, (for the purpose of competition or personal gain).or pass on to others, any information or documents provided by the Principal/Owner as part of the business relationship, regarding plans, technical proposals and business details, including and business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.

   (d) The Bidder (s) /Contractor(s) of foreign origin shall disclose the names and addresses of agents/representatives in India, if any Similarly Bidder(s)/Contractor(s) of Indian Nationality shall disclose names and addresses of foreign agents/representatives, if any. Either the Indian agent on behalf of the foreign principal or the foreign principal directly could bid in a tender but not both. Further, in cases where an agent participate in a tender on behalf of one manufacturer, he shall not be allowed to quote on behalf of another manufacturer along with the first manufacturer in a subsequent/parallel tender for the same item.

   (e) The Bidder (s)/Contractor (s) will , when presenting his bid, disclose (with each tender as per proforma unclosed) any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the Contract.

3) The Bidder(s) /Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.

4) The Bidder(s)/contractor(s) will not, directly or through any other person or firm indulge in fraudulent practice means a willful misrepresentation or omission of facts or submission of fake/forged documents in order to induce public official to act in reliance thereof, with the purpose of obtaining unjust advantage by or causing damage to justified interest of others and /or to influence the procurement process to the detriment of the Government interests.

5) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm use Coercive Practices (Means the act of obtaining something, compelling an action or influencing a decision through intimidation, threat or the use of force directly or indirectly, where potential or actual injury may befall upon a person, his/her reputation or property to influence their participation in the tendering process).

Article 3: Consequences of Breach

Without prejudice to any rights that may be available to the Principal/Owner under law or the Contract or its established policies and laid down procedures, the Principal/Owner shall have the following rights in case of breach of this integrity Pact by the Bidder (s)/Contractor(s) and the Bidder(s)/Contractor(s) accepts and undertakes to respect and uphold the Principal /Owner's absolute right:

1) If the Bidders) / Contractor(s), either before award or during execution of Contract has committed a transgression through a violation of Article 2 above or in any other form, such as to put his reliability or credibility in question, the Principal/owner after giving 14 days notice to the contractor shall have powers to disqualify the Bidder (s)/Contractor(s) from the Tender process or terminate/determine the Contract, if already executed or exclude the Bidder/Contractor from future contract award processes. The imposition and duration of the exclusion will be determined by the severity of transgression and determined by the Principal/owner. **Such exclusion may be forever or for a limited period as decided by the Principal/owner.**

2) **Forfeiture of EMD/performance Guarantee/Security Deposit:** If the Principal/owner has disqualified the Bidder(s) from the Tender process prior to the award of the Contract or terminated/determined the Contract or has accrued the right to terminate/determine the Contract according to Article 3(1), the Principal /Owner apart from exercising any6 legal rights that may have accrued to the Principal/Owner, may in its considered opinion forfeit the entire amount of Earnest Money Deposit, Performance Guarantee and security Deposit, Performance Guarantee and security Deposit of the Bidder/Contractor.

3) **Criminal Liability**: If the Principal/Owner obtains knowledge of conduct of a Bidder or Contractor, or of and employee or a representative or an associate of a Bidder or Contractor which constitutes corruption within the meaning of Indian Penal code (IPC)/Prevention of corruption Act, or if the Principal/owner has substantive suspicion in this regard, the Principal/owner will inform the same to low enforcing agencies for further. Investigation.

Article 4- Previous Transgression

1) The Bidder declares that no previous transgressions occurred in the last 5 years with any other Company in any country confirming to the anticorruption approach or with Central Government or State Government or any other Central/State Public sector Enterprises in India that could justify his exclusion from the Tender process.

2) If the Bidder makes incorrect statement on this subject, he can be disqualified from the Tender process or action can be taken for banning of business dealings/ holiday listing of the Bidder/Contractor as deemed fit by the Principal/owner.

3) If the Bidder/Contractor can prove that he has resorted / recouped the damage caused by him and has installed a suitable corruption prevention system, the Principal/owner may, at its own discretion, revoke the exclusion prematurely.

Article 5- Equal Treatment of all Bidders/Contractors/Subcontractors

1) The Bidder(s) /Contractor(s) undertake(s) to demand from all subcontractors a commitment in conformity with this Integrity Pact. The Bidder/Contractor shall be responsible for any violation(s) of the principles laid down in this agreement /pact by any of its Sub-contractors/sub-vendors.

2) The Principal/owner will enter into Pacts on identical terms as this one with all Bidders and Contractors.

Article 6- Duration of the Pact

This Pact begins when both the parties have legally signed it. It expires for the Contractor/Vendor 12 months after the completion of work under the contract or till the continuation of defect Liability period, whichever is more and for all other bidders, till the Contract has been awarded.

If any claim is made/lodged during the time, the same shall be binding and continue to be valid despite the lapse of this Pacts as specified above, unless it is discharged /determined by the competent authority, HLL Biotech Limited.

Article 7- other Provisions

1) This Pact is subject to Indian Law., place of performance and jurisdiction is the Head quarters of HLL Biotech Limited of the Principal/Owner, who has floated the Tender.

2) Changes and supplements need to be made in writing. Side agreements have not been made.

3) If the Contractor is a partnership or a consortium, this Pact must be signed by all the partners or by one or more partner holding power of attorney signed by all the partners or by one or more partner holding power of attorney signed by all partners and consortium members. In case of a company, the Pact must be signed by a representative duly authorized by board resolution.

4) Should one or several provisions of this Pact turn out to be invalid; the remainder of this Pact remains valid. In this case, the parties will strive to come to an agreement to their original intensions.

5) It is agreed term and condition that any dispute or difference arising between the parties with regard to the terms of this Integrity Agreement/pact, any action taken by the Owner/Principal in accordance with this **Integrity Agreement/Pact or interpretation thereof shall not be subject to arbitration.**

Article 8- LEGAL AND PRIOR RIGHTS:

All rights and remedies of the parties hereto shall be in addition to all the other legal rights and remedies belonging to such parties under the Contract and /or law and the same shall be deemed to be cumulative and not alternative to such legal rights and remedies aforesaid. For the sake of brevity, both the Parties agree that this Integrity Pact will have precedence over the Tender /Contact documents with regard any of the provisions covered under this Integrity Pact.

IN WITNESS WHEREOF the parties have signed and executed this Integrity Pact at the place and date first above mentioned in the presence of following witnesses:

……
(For and on behalf of Principal/owner)

……
(For and on behalf of Bidder/Contractor)

WITNESSES:

1.

(Signature, Name & address)

2.

(Signature, Name & address)

Place:

Date:

Section XXII

Deleted

Section XXIII
SCHEDULE OF FISCAL ASPECTS

Sr. No.	Particulars	Description
1	Submission of completed Tender	17-10-2014, 16:00 Hrs
2	Opening of Technical Bid	17-10-2014, 16:30 Hrs
3	Delivery	10 (Ten) months from date of issue of Purchase order
4	Installation, commissioning and validation	2 (two) months from the delivery of the equipment at site
5	Advance	10% of the contract value against Bank Guarantee equivalent to 110% of the advance amount and submission of Security Deposit/ Performance Security of 5% of contract value from a Scheduled Commercial Bank . In case of Foreign tenderer, the bank guarantee shall be routed through a Scheduled Commercial Bank in India.
6	Payment terms	As mentioned in GCC: Clause. 21
7	Liquidated damages/per week	0.5% per week inclusive of Sundays & Holidays upto a maximum of 5% of Contract Value
8	Warranty Period	12 (Twelve) months from the date of Completion.
9	Earnest Money Deposit	Rs. 2.87 Million
10	Refund of Earnest Money Deposit to unsuccessful bidders	On award of contract to successful bidder
11	Insurance & Transportation	On account of Supplier
12	B.G/ DD to be in favor of	HLL Biotech Ltd., Chennai
13	All queries / communication to be addressed to	The Chief Executive Officer HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113 Email: ramanr@hllbiotech.com, Contact No: 044 22544949 - 78, Fax – 044 22540101
14	Pre-bid Meeting	**Venue:** HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113 **Date and Time : 26.09-2014 at 11:00 Hrs**
(Contractor)		**(Employer)**

Installation Requirement Specification and Specific Instructions

Table of Contents

1.0 Approval Signatures

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of HLL BIOTECH LIMITED, and authorized by the appropriate Project Authority.

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Shilpa Rao K V	Senior Project Engineer- Biotech	Shilpa Rao K.V	23/03/2014
Checked by			
Mr. Sridhar Babu K	Assistant Manager	K.Sridhar Babu	24/03/2014
Approved by			
Mr. Vikas Katial	GM - Head COC Vaccines	Vikas Katial	26 March 2014

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
B. Sathesh	Manager-(VV)		26/03/2014
CH. LAKSHMI PUNNARAO	DM (BVP)		26/03/2014
K Radha Krishnan	DM (Measles)		26/03/2014
T. VIGNESHWARAN	AM-PROJECTS		26/3/14
Approved By			
G. Narasimha Reddy	Sr. Manager		26.03.2014
Dr. R. KUMARAN	DVP(P)		26.03.2014

Dr. Muthiah	Project Head (I/C)		26/03/14
D. SURESH BABU	DGM (QA & EHS)	D. Suresh Babu	26.03.2014
Authorized by			
Rajesh K Gupta	COO		27.03.14

Specifications	Remarks
2.0 Overview	
2.1 Project Introduction	
HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India, is implementing "Integrated Vaccines complex" Chengalpattu. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India. HLL Biotech Limited has associated with NNE Pharmaplan India Limited, hereinafter called as "NP" has been appointed as "Engineering Consultants". NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices. This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian FDA (Schedule M), WHO/GMP regulations.	
2.2 Project Standard	
The facilities, upon completion, shall be in compliance with the Indian FDA (Schedule M), WHO, and also the HBL's internal quality standards.	
2.3 Purpose	
This specification states the mandatory requirements and critical instructions for process systems, process support systems and utility systems.	
3.0 Scope	
3.1 Systems in scope	
The specification applies to process systems, process support systems and utility systems used for producing vaccines. For each requirement (see section 5.0 "Requirement specification"), it is more explicitly specified what types of systems the requirements apply to. The specification applies both to new systems and to changes of existing systems (if applicable and then only to the parts that are changed). HVAC systems, automation and electrical building installations are not included in the scope.	

Specifications		Remarks
3.2	**Supplementary or changed requirements**	
	The specification covers mandatory requirements and critical instructions. There may be cases when more specific requirements than described in this specification are necessary. It may be supplementary requirements; In such cases, the User Requirement Specification (URS) must state which requirements are applicable and where precisely deviations are made from this instruction	
3.3	**Note**	
	"**Vendor** is required to adhere to all necessary and applicable requirements. Any specific requirement not applicable should be mentioned in the remark column. Also, any deviation or non-compliance a comment must be inserted or enclosed as a separate annexure by referring to the respective IRS specification number." For more information vendor to refer Tender enquiry document	
4.0	**Safety Requirement**	
4.1	**General**	
	Following facilities must be provided to protect personnel, product and equipment / system:	
4.1.1	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.	
4.1.2	Noise level <75 db at a distance of 1 meter from the equipment / system.	
4.1.3	Emergency stop switch should be located on accessible areas or within the reach of the operator and a signal has to display when emergency stop button was activated..	
4.1.4	Earthing all parts of the machine, including doors, movable units etc to the earth grid/cable/tag box, supplied by the electrical contractor	
4.1.5	In case of power failure, the system must be protected in the following priority and the likeliness of damages must be minimized: • Persons and environment • Equipment • Product	
4.1.6	For the safety of the operator the external surfaces should not have temperature more than 45°C.	
4.1.7	Warning stickers on all hot surfaces	
4.1.8	Appropriate closure of all rotating parts of machine.	
4.1.9	Appropriate failure detection and alarm notification	

	Specifications	Remarks
4.1.10	All machine doors which are closed during production, according to operator safety, have to be supervised by security switches. In case of door opening the machine must stop immediately.	
4.1.11	Explosion proof design.	
4.1.12	Motor fault or over load.	
4.1.13	Sufficient lighting inside machine housing and control cabinets must be provided by the vendor.	
4.1.14	Vibrations shall not exceed level acceptable according ISO 10816.	
4.1.15	All lines and equipment surfaces which represent a danger to operators and maintenance personnel with regard to freezing or burns will be adequately insulated.	
4.1.16	Generally all sensors are supplied via the uninterruptible network. Thus the actual system condition can be displayed even in case of voltage failure.	
4.1.17	Control lights and other display elements shall not be influenced by voltage failure.	
4.1.18	Grounding of the entire framework is required	
4.1.19	All motors have to be thermally protected	
4.1.20	The level of protection of the electrical components has to be IP54 or higher based on the Process requirements.	
4.1.21	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms.	
4.1.22	As per the state electricity board, harmonics for all electrical wiring should remain within 3%. Active or passive filters should be used. The same has to be clearly marked in circuit diagrams. Detailed information to be provided in spare lists etc	
4.2	**Power Failure and Recovery**	
4.2.1	On power failure inimize hall come to rest to protect operator, equipment and the product.	
4.2.2	After power resumption, the machine should not start automatically i.e. human intervention should be required.	
4.2.3	After power regain, the machine should start from the step it stopped with the provision of real time recording and printing facility.	

Specifications	Remarks
5.0 Requirement specification	
5.1 **Refrence Standard / Guideline for Equipment / System**	

The equipment should comply with the following guidelines / standard:

Sl. No.	Reference Standard / Guideline	Applicability
1.	**Current GMP-Regulations** • EU-GMP-Guideline Part 1, Annexes 1, 11 & 15Schedule "M" GMP • 21 CFR, Part 210 cGMP in Manufacturing, processing, packing or holding of drugs: General • 21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals • WHO Good Manufacturing Practices – Main Principles for Pharmaceuticals Products • WHO Good Manufacturing Practices for biological products **Operating safety act** • The requirements of the Operating safety act must be observed. **ASME-BPE compliance** • ASTM, American Society of Testing Materials • ANSI, American National Standard Institute • AWS, American Welding Society	General requirement for all the equipments / systems (pharmaceuticals/biologics/vaccines)

Sl. No.	Reference Standard / Guideline	Applicability
2.	**FDA Guidance for Industry** Sterile Drug Products Produced by Aseptic Processing-cGMP	For all equipments/systems used in aseptic manufacturing
3.	**FDA Guidance for Industry** Documentation for Sterilization Process Validation in application for human and veterinary drug products	For equipments used in sterilization such as autoclave / DHS etc
4.	**GAMP** The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 5 **Current GMP-Regulations** 21 CFR Part 11: Electronic Records; Electronic Signatures	For automated / semi – automated computerized systems

	Specifications		Remarks
5.	**CE Conformity** A CE declaration of conformity must be available. The CE identification must comply with the current EC commission	For products placed on the market in the European Economic Area (EEA) (all the systems / equipments).	
6.	**ASME** Section 8- Div I for pressure vessels design ASME-BPE Compliance (As per latest version)	For all pressure vessels / reactors / inimize / autoclave / sterilizers etc	
7.	**ANSI / NSF 49-2008** Biosafety Cabinetry : Design, Construction, Performance and Field Certification	Biosafety cabinet	
8.	**ISO 14664** Clean Rooms and its Associated Controlled Environment **(European Standard) EN – 1822 for HEPA FILTERS**	Any equipments with HEPA filters (RABS / LAF / BSC etc)	
9.	**ISO 8362** Injection containers for injectables and accessories	For Vials and closures	

5.2	**Cleaning Requirement**	
5.2.1	Design of equipment should be smooth to enhance cleaning feasibility and by providing zero sharp corners, crevices and smooth weld joints.	
5.2.2	All bolts, nuts on the exterior part of equipment will be with cap head or cap nut	
5.2.3	The vendor shall provide the detail of cleaning agent based on compatibility of material.	
5.2.4	Equipment contact parts shall be easily dismantle-able and cleanable	
5.2.5	The equipment shall be easily accessible for cleaning of non-product contact part at maintenance side of the system	
5.2.6	All gaskets provided to avoid leakage should be able for easy removal & re- fixing.	
5.2.7	The vendor shall provide the detail of utilities requirement for the applicable cleaning (WIP / CIP / SIP).	
5.2.8	Systems with CIP shall be designed for 100% coverage of the internal surface areas.	
5.3	**Qualification Requirement**	
5.3.1	Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) and the performance phase (PQ). Computer system verification as per the standards of GAMP.	
5.3.2	Vendor shall support and provide all necessary documents and test procedures to client	

	Specifications	Remarks
	for proper execution of all the qualification phases.	
5.4	**Material of Construction (MOC)**	
5.4.1	Materials:	
	Materials: Surfaces in contact with media must be of a material quality which does not react with to, absorb, leach or contaminate the media to an extent that will impact the product quality. The materials specified in row must always be evaluated in relation to the specific media that the material will get in contact with. Particular limitations regarding the use of materials shall be specified in the respective URS.	
	Acid-proof stainless steel, resistance: Many types of acid-proof stainless steel are not sufficiently resistant to media with low pH (under ~3) or high chloride content, particularly HCl solutions. Where acid-proof stainless steel is not sufficiently resistant PP, PE, PVDF or PTFE are recommended.	
	Declaration of Compliance: Materials of construction must as a minimum be documented with a Declaration of Compliance from the supplier. The Declaration must contain a guarantee that the used/supplied materials are in compliance with the specified/ordered. Suppliers of pipes, fittings, components, instruments and systems must be able to trace the materials to the material manufacturer's "heat number" and the material composition of the specific batch. The supplier's ability to secure this traceability can for instance be ensured via supervision, audit and performance history as part of the approval of the supplier.	
	Specifications:	
	• All metallic product contact / critical surfaces should be constructed of SS316 L grade with internal mirror finish (< 0.5µ Ra for filling line and < 0.8µ Ra for lyophiliser) and external surface matte finish (< 1.2µ Ra).	
	• All metallic non-product / noncontact / non critical surfaces should be constructed of SS304 grade or better (316 in sterile area) with external surface finish as matte finish (< 1.2µ Ra).	
	• Gaskets, seals and O-rings coming in direct / indirect contact surfaces should be constructed of USFDA approved polymeric materials only.	
	• Borosilicate glass should be used wherever required eg:- inspection door viewing port in the machine etc.	
	• Material of insulation shall be mineral wool/ ceramic wool cladded with SS 304.	
	Area of application: The requirements apply to process systems and clean utilities. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests.	
	Alternative materials listed below. • **Acid-proof stainless steel** with content of	

Specifications	Remarks
○ Molybdenum ≥2.0% and Carbon ≤ 0.03%. • *For example: AISI 316L, AISI 904L, EN1.4404, EN1.4435, EN1.4462,* • *EN1.4539, UNS S32205, others.* • Also accepted: AISI 316Ti and EN1.4571. • If the material is not to be welded, accepted are also: ○ Molybdenum ≥ 2.0% and Carbon ≤ 0.08%. • *For example: AISI 316, EN1.4401, others.* • **Polymers**, accepted types: • CSM (Hypalon), E-CTFE, EPDM/EPD, FEP, FFKM, FPM (Viton), PE, PEEK, • PFA, PP, PTFE (Teflon), PVDF, SI. • In LPLC columns: acrylic • In addition, the material must comply with 21 CFR part 177 or USP 24 Class VI. • **Liquids** must comply with 21 CFR part 172 or part 178. • *By "liquids in contact with media" is here understood lubricants and other liquids in equipment, components and instruments where there is a high probability of direct contact with the medium by wear and tear, defects, failures, etc.* • **Other materials**, accepted types: ○ Titanium *e.g. EN3.7025, EN3.7035, EN3.7235* ○ Hastelloy *e.g. C4, C22, C276* ○ Ceramics *e.g. alumina, zirconia* ○ Glass*e.g. borosilicate* ○ In mechanical seals and the like, also SiC and WC.	
5.4.2 **Untreated welds**	
Welds: Untreated welds in contact with media must have a sanitary finish. This facilitates easy and effective cleaning and minimise the risk of corrosion, microbial growth and other contamination of the product. For treated (burnished, polished) welds in stainless steel, Plastic welds are not treated.	
100% inspection of all welds is not required. The quality of the welds is instead secured through a number of indirect requirements and spot checks and welder qualification.	
Few welds: In cases when only a few welds are to be carried out, a 100% independent inspection can be chosen instead of the 5% stated in requirement a) In that case, requirements on certificates (b,2) and 20% self-inspection (b,4) are cancelled.	
Self-inspection: By self-inspection is meant an inspection that is carried out by the welding contractor's inspection function.	
Independent inspection: By independent inspection is meant an inspection carried out by a Technical Discipline Specialist who is organisationally independent from the welder. It is recommended to use Technical Discipline Specialists from a organisation with accreditation to perform welding inspections.	
Extended inspection: If the inspection uncovers welding defects or discolorations, the	

Specifications	Remarks
inspection must be extended to determine the extent of the problems (for instance by systematic inspection of the specific welder's work).	
Pickling: For welds in stainless steel there may be cases where it is very difficult to achieve welds without too much discoloration. In such cases, pickling or passivation is acceptable, but it is not recommended as a general procedure.	
Specifications:	
• All welds shall be crack and crevice free.	
• Internal welds and welds likely to be in contact with the product shall be ground smooth and flush. All other welds shall be ground smooth (< 1.2µ Ra).	
• Clean media pipes shall be orbital welded	
• All welds shall be polished to the same standard as the surrounding areas, with direction of lay following the direction of welding.	
• Insulation material should be non-fibrous and covered with completely welded SS 304 or better cladding.	
• Stainless steel fabrications must be welded under inert gas (Orbital welding) with Boroscopy records and treated by pickling and passivation to pharmaceutically accepted standards, to prevent corrosion.	
Area of application: The requirements apply to process systems. For systems with dry gases there are however no requirement for independent inspection (part of requirement a), and the requirement is verified by commissioning. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests.	
A] Untreated welds in stainless steel in contact with media must be without welding defects – as defined in [ASME BPE, MJ-6] or equivalent standard. Discoloration exceeding "light straw" or "light blue" must not exist in the heat-affected zone (cf. [AWS], [Force] or equivalent standard). At least 5% of a system's welds must be inspected for discoloration and welding defects by an independent Technical Discipline Specialist. The inspection must be targeted the welds that the independent Technical Discipline Specialist considers hardest to make error-free and the inspection must representatively be spread on the welders. The inspection must be carried out using boroscopy, endoscopy or direct visual inspection.	
B] Untreated welds in stainless steel in contact with media must be: 1. Traceable to welder, welding procedure and self-inspection via a welding log. 2. Made by welders holding a valid welding certificate to weld in the specific materials and dimensions. The certificate must be issued by an accredited authority *(for example Force Technology and others).* 3. Executed according to an approved welding procedure (WPS). 4. Self-inspected by sampling for welding defects and discoloration (cf. req. a). The inspection must be carried out using boroscopy, endoscopy or direct visual inspection.	

	Specifications	Remarks
	The self-inspection must be carried out on at least 20% of the welds. The inspection must be targeted the welds which the construction supervision staff considers hardest to make error-free and the inspection must be representatively spread on the welders.	
	C] Welds in thermoplastics, in contact with media must be 1. Without welding defects – as defined in [ASME BPE, PM-3.4.1] or equivalent standard. 2. Made by fusion welding with a machine where data for critical welding parameters is recorded automatically. 3. "Beadless butt fusion" type welds in systems with formal requirements to drain ability (see section title "drain-ability). 4. Traceable to welder, welding procedure and welding data via a welding log. 5. Made by welders who hold a valid welding certificate to weld the specific materials. The certificate must be issued by an accredited authority, alternatively an authority approved by the material supplier. 6. Executed according to an approved welding procedure (WPS).	
5.5	**Use of Lubricants**	
5.5.1	Any lubricant, if used in the equipment / system must be of food grade and non-toxic.	
5.5.2	If lubricant use, All lubricating points must be clearly shown and labeled.	
5.6	**21 CFR Part 11 Compliance**	
5.6.1	Automation and Human Machine Interface (HMI); the software/Hardware system should generate data that cannot be manipulated by the operator. Compliance to 21CFR part 11.	
5.6.2	Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software if used to generate, process, store the critical data must be validated and must be upgradeable to 21 CFR Part 11 requirements.	
5.6.3	The vendor may be also allowed to use CAT6 or CAT6a cables,(RJ-45) cables to do communication	
5.6.4	RS 232 interface is required to transfer the data and as well to take the printout.	
5.6.5	A backup of the data must be available on the system, locked and not tampered by the operator. The data must not be able to manipulated by the operator.	
5.6.6	The audit trail for the data integrity may need to include functions such as authorized user, creations, links, embedded comments, deletions, modifications/corrections, authorities, privileges, time and date etc.	
5.6.7	**Area of application:** This requirements apply to all types of critical process equipments and utility systems (such as BMS of HVAC, PW, WFI & PSG) with HMI, PLC / Software	

Specifications		Remarks
5.7	**Data Integrity**	
5.7.1	System security shall be provided to access the operation system and to alter configurable parameter values through access password.	
5.7.2	Minimum 3 level password shall be provided as: • **Operator:** Shall provide operator access to allow routine operation of all equipment features • **Supervisor:** Shall provide access to operator level features in addition to critical operating parameter configuration • **System Administrator:** Shall provide the access to the Operator and Supervisor level features in addition to system security parameters.	
5.7.3	**Area of application:** This requirements apply to all types of critical process equipments and utility systems (such as BMS of HVAC, PW, WFI & PSG) with HMI	
5.8	**Batch Data Display and Record Printing**	
5.8.1	**A complete batch display indicating the following important parameters, but not limited to these:**	
5.8.1.1	Start date and time of operation	
5.8.1.2	End date and time of operation	
5.8.1.3	Product name and Batch No (For process equipments)	
5.8.1.4	All failures alarms (/repeated alarm) and notification	
5.8.1.5	Operator code and name	
5.8.1.6	All process parameters	
5.8.2	**A batch record indicating the following important parameters but not limited to these**	
5.8.2.1	Product name and Batch No (For process equipments)	
5.8.2.2	Start date and time of operation	
5.8.2.3	End date and time of operation	
5.8.2.4	All failures alarms (/repeated alarm) and notification	
5.8.2.5	Operator code and name	
5.8.2.6	Adequate space for writing remarks / corrective actions if any.	

Specifications		Remarks
5.8.2.7	Identified space to sign for operator & supervisor.	
5.8.3	**Area of application:** This requirements apply to all types of critical process equipments and utility systems such as PW, WFI & PSG	
5.9	**Desired Documents**	
5.9.1	Vendor must generate all applicable documents during all phases of equipment fabrication i.e. design fabrication, testing and shipment as per applicable standards.	
5.9.2	Following documents, but not limited to these, are expected from the vendor as part of the supply package as hard copy (02 No.) and electronic editable versions in **English** language:	
5.9.3	**Phase 1: Pre-ordering of the equipment**	
5.9.3.1	Filled in URS	
5.9.3.2	Equipment layout drawing fitted in the room layout block	
5.9.3.3	Detail technical offer that support the compliance of the URS must include the make of the components and P&ID Proposal.	
5.9.4	**Phase 2: Post-ordering and pre-fabrication stage of the equipment**	
5.9.4.1	Functional design specification and technical specification, that should contain the following:	
5.9.4.1.1	Equipment descriptions and its function	
5.9.4.1.2	Equipment operation steps	
5.9.4.1.3	HMI functions with screen shot	
5.9.4.1.4	List of failure indications	
5.9.4.1.5	List of interlocks	
5.9.4.1.6	List of input/outputs and its functions	
5.9.4.1.7	Critical list of major component, devices and instruments with their specific functions, specifications data sheet	
5.9.4.1.8	Schematic/GA drawings of the equipment.	
5.9.4.1.9	List of article contact surface and its MOC	
5.9.4.2	Based on the above documents, equipment design shall be evaluated and approved by the user for the fabrication.	
5.9.5	**Phase 3: Fabrication stage of the equipment & FAT**	

	Specifications	Remarks
5.9.5.1	Vendor shall provide the Factory Acceptance Test (FAT) protocol at least 4 weeks in advance of the date of FAT, for the approval by the user.	
5.9.5.2	Internal FAT reports compiled by vendor should be shared with the client for reference.	
5.9.5.3	Vendor shall arrange the necessary raw materials (vials, rubber bungs etc) to demonstrate the following tests like productivity, synchronization etc	
5.9.6	**Phase 4: Delivery of the equipment & SAT**	
	Delivery of the Equipment:	
5.9.6.1	Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.	
5.9.6.2	Operation and maintenance manuals, preventive maintenance schedule (with recommended consumables and recommended time interval) for equipment's major component as well as the operating system	
5.9.6.3	Operation and maintenance manuals for the bought out items.	
5.9.6.4	Installation instructions/ guideline for equipment	
5.9.6.5	Final as-built drawing for equipment.	
5.9.6.6	Detailed drawing (plan and minimum one elevation) marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities on the drawing along with the offer.	
5.9.6.7	Other applicable drawings (such as P&ID, electrical, instrumentation etc.)	
5.9.6.8	Spare and/ or change parts list with ordering information	
5.9.6.9	MOC certificates for all direct/ indirect product contact surfaces.	
5.9.6.10	Detailed description of all components with the manufacturer name, code/sr. no., function, MOC, different test reports, manuals with the installation guideline of different components (as applicable) etc.	
5.9.6.11	Equipment, components, valves and instrumentation etc. shall be uniquely identified by some code / numbering system and the same shall be shown in Process & Instrumentation (P&I) and General Arrangement (GA) drawings.	
5.9.6.12	Instrument calibration certificates with respect to the traceable national reference standard instrument and their calibration procedure. Original calibration certificate along with traceability to be submitted by vendor in their IQ file.	
5.9.6.13	Different reports like Welding, Boroscopy, Passivation etc. (whichever is applicable)	

Specifications		Remarks
5.9.6.14	Recommended SOPs for operation (Start-up and shutdown), general cleaning and maintenance of each equipment	
5.9.6.15	Guarantee/ warranty certificates for each equipment and major bought-out items, such as PLC, printer, recorders, instrumentation etc.	
5.9.6.16	Software installation CD with 2 back-ups, wherever applicable.	
5.9.6.17	Software recovery procedures in case of computer system breakdown, for equipment control system, wherever applicable.	
5.9.6.18	Vendor must generate and provide all specifications and test certificates of software used in the equipment control and/or monitoring system.	
5.9.6.19	Shipping checklist along with size & gross weight of each equipment	
5.9.6.20	IQ and OQ protocols	
5.9.6.21	Control System input / output verification data and report (Optional)	
5.9.6.22	Types of Lubricant and Lubrication instructions. Food grade certificate	
	Documentation & Drawing Requirement	
5.9.6.23	All documents have to be supplied as Hard copy, PDF and native file (doc, xls, ppt, dwg, etc.).	
5.9.6.24	All documents have to be archived in DIN A4 binders. Larger formats have to be folded according to the requirement.	
5.9.6.25	Each binder must be marked with the binder number and number of binders.	
5.9.6.26	Different documents within a binder must be separated by extra separator sheets	
5.9.6.27	A Table of content is necessary for the whole documentation.	
5.9.6.28	User manual: Descriptions and manuals must contain all necessary information about safety, installation, commissioning, operation, maintenance and troubleshooting.	
5.9.6.29	If an initial calibration will be not carried out, at least a manufacture's calibration certificate must be delivered.	
5.9.6.30	Software back-up copies must be delivered for all used programmes to restore the system or software status quo ante.	
5.9.6.31	The drawing or document number must be clearly identifiable.	
5.9.6.32	Author/date of creation and reviewer/date of review have to be listed on each drawing, plan and diagram.	

Specifications		Remarks
5.9.6.33	The scale must be declared.	
5.9.6.34	The size and format of the drawings, plans and diagrams have to be selected in such a way that all information is readable.	
5.9.6.35	All drawings and diagrams must be supplied in AutoCAD compatible formats.	
5.9.6.36	A legend including a clear designation must be issued for all used symbols.	
5.9.6.37	Appropriate block diagrams must be developed in case of complex equipment.	
5.9.6.38	The process flow inside of the equipment must be displayed in a clear and balanced manner e.g. with arrows and text.	
5.9.6.39	The flow directions of the media must be displayed in the drawing.	
5.9.6.40	Main dimension and all dimensions of connections to other systems must be indicated.	
5.9.6.41	Equipment with the requirement of drainability must be indicated with slope and direction of slope.	
5.9.6.42	Software ladder logic/ operation and controls flow charts	
5.9.6.43	Biological compatibility certificates of all non metallic parts	
5.9.6.44	The vendor to work out a list showing all documents included in his scope of work and delivery.	
5.9.6.45	All documents require a document control Section listing all versions and indicating executed modifications.	
5.9.6.46	Delivered software must be forwarded on suitable Storage medium in a format suitable for installation. Source codes for Client specific applications must be handed over as electronic files.	
5.9.6.47	If cables have to be pulled by third parties, cable lists with following information are required: unique cable ID-No, cable type, start and endpoint, differentiation between power and control cable, particular requirements.	
5.9.6.48	If the equipment has a control system, all PLC components like I/O-cards and local units like bus nodes, valve terminals or control panel must be listed with information at least about tag name, description, type, vendor's item number and a reference to the appropriate manual with the installation guideline.	
5.9.6.49	Other components next to the PLC like frequency converter, servo controller, electronic cams, transmitter, etc. all single items must be listed with information at least about tag name, description, type, manufacture, and a reference to the appropriate manual books with the installation guideline.	
5.9.6.50	If the equipment contains PCs, the performance data of the PC with processor type/manufacture/tact frequency/hard disk size and RAM must be labeled. Peripheral	

Specifications	Remarks
apparatus like I/O-cards, graphic cards, etc. which do not operate with standard drivers must be indicated and must also be contained information at least about the description, type, manufacture and a reference to the appropriate manual books with the installation guideline.	
5.9.6.51 Supplementing the P&I diagram: A valve position matrix must be developed for complex processes. The conditions of valves and engines must be described in the various process steps.	
5.9.6.52 If the plant is equipped with a PLC, a print of the programming environment must be generated and printed.	
5.9.6.53 Calibration certificate should have validity of at least 12 months from the date of installation	
5.10 Training Requirement & Support	
5.10.1 A special training for operators, supervisor, and maintenance, electrician staff (min. 5 days each) has to be included in the offer.	
5.10.2 Training must be carried out by qualified personnel. Training documents must be handed over to each participant at the beginning of the training. A training certificate describing the training subjects must be worked out.	
5.10.3 Training documentation to be issued for operator's easy handling and error analysis.	
5.10.4 The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.	
5.10.5 The Vendor shall provide a four (at least 4) hour training course to twelve (12) maintenance people on troubleshooting and repair of the system.	
5.10.6 A concise operating instruction shall be issued containing e. g. pictures for operator's easy understanding of the process.	
5.10.7 Maintenance to be carried out must be clearly and plainly described. Description of the maintenance of all components to be summarized in one document.	
5.10.8 Vendor should specify the in-house strength / capabilities and offer to support for the process validation and optimization of the actual process cycle.	
5.10.9 The Vendor shall provide a twenty-four (24) hour technical support phone number with a maximum of thirty (30) minute response time to calls requesting assistance. Support personnel for this hotline must be knowledgeable and professional.	
5.11 GMP Requirement	
5.11.1 A clear separation between clean and technical area must be realized.	
5.11.2 All utility line shall be properly identified with direction	

Specifications	Remarks
5.11.3 All drives, filters, pumps, valves (specially chamber drain) should have easy access	
5.11.4 The sterile filters must be testable for integrity. Vendor should provide the certification with Test procedure for Integrity and no of sterilization cycle in the Certificate.	
5.11.5 For all clean media a sampling valve should be provided at supply and in drain. Sampling valve should be certified 1.5D requirement for Dead leg.	
5.11.6 An appropriate seal must be used for connecting the paneling to the suspended ceiling, clean room walls and floor.	
5.11.7 The front paneling of the system installed in clean room must be gas tight to the technical area of the system	
5.11.8 The bio-seal provided for aseptic area equipment should be air tight.	
5.11.9 **P&ID Diagram**	
P&I diagrams: are the basis for detailed design, correct functionality, process understanding, maintenance and tracing of the components and instruments in a system. P&I diagrams must therefore be available that have each single component and instrument unambiguously defined by a tag. The plant must be verified to be constructed according to the P&I diagrams and they must subsequently be maintained "as built".	
Components: Every tagged component/instrument on the P&I diagrams must be registered (in databases or lists) with information that supports correct maintenance. Relevant information includes: manufacturer, type, model, dimensions and materials of construction.	
Data sheet, Maintenance instruction: A data sheet and maintenance instructions must be available for each component/instrument type (can be combined in one document).	
Tamper proof Tag numbers: Marking of tags must be executed in a quality that secures durability and resistance to the environment where they are placed (for example temperature, humidity, sunlight).	
Specification:	
• Upon equipment delivery, Vendor shall supply client with a register containing all details of component numbers issued.	
Area of application • Pipes must be laid out according to P&I-diagram. • Where slope on pipes are marked on the P&I diagram, slope must be established with the indicated direction. • Where drainage to drain systems is marked on the P&I diagram, air break must be established. • Placement of components and instruments must be mutually correct according to the P&I diagram. • Components and instruments must be marked with the tag shown on the P&I diagram.	

Specifications	Remarks
• Components and instruments must be drawn on the P&I diagram with the correct symbol. • Components and instruments must be registered on component/instrument lists with correct tag, type and manufacturer.	
Component and instrument databases (or lists) must, for each component / instrument, contain data for • Type • Manufacturer • Model • Dimensions • Materials of construction For each component / instrument type, a datasheet and maintenance instructions must be available.	
5.11.10 **Sanitary components**	
Sanitory Components: All process equipment (including couplings, fittings and clamps) in contact with non-bacteriostatic media must be of a sanitary type. This facilitates easy and effective cleaning and minimise the risks of microbial growth and other contamination of the product. Whether the equipment can be considered to be sanitary must be assessed based on international, accepted standards for sanitary designs, for example EHEDG Guidelines, 3-A Sanitary Standards or ASME's Bioprocessing Equipment [ASME BPE].	
Specification:	
• All valve and fitting in contact with the media shall be of sanitary type and suitable for aseptic use	
Area of application: The requirements apply to process systems. The requirements are however not relevant to: • Systems with dry gasses. • Self-draining pipe branches in systems with pure steam. A] Tanks, centrifuges, pumps and other process equipment, as well as components and instruments, must be of a sanitary type. B] Couplings, fittings and clamps must be of a sanitary type.	
5.11.11 **Prevention of cross-contamination**	
Cross Contamination: Process systems must be designed so that the risk of cross-contamination is minimised between media that must not get in contact with each other. Prevention against cross-contamination through leaking valves must always be established between CIP systems and other media and always between water systems and other media". Whether the systems must be secured against leaking valves between other media one to another is assessed individually and must be stated in the system's URS or other requirement specifications, and must also be reflected in the	

Specifications	Remarks
design solution.	
Double Block and Bleed: Process systems must be designed so that the risk of cross-contamination is minimised between media that must not get in contact with each other. Prevention against cross-contamination through leaking valves must always be established between CIP systems and other media and always between water systems and other media". Whether the systems must be secured against leaking valves between other media one to another is assessed individually and must be stated in the system's URS or other requirement specifications, and must also be reflected in the design solution.	
Heat exchangers: Heat exchangers must be of the type double-plated heat exchanger or double tube-sheet tubular heat exchanger (Ref section title "sanitary components"), where leaks are detectable on the outside.	
Air break: Drainage towards drains must be secured against reverse suction and contamination with air breaks. Alternatively, a suitable sanitary mechanical device may be used, if the drain connection needs to be closed.	
Area of application: a] The requirements only apply to process systems. Design solutions must be chosen that prevent cross-contamination through leaking valves • Between CIP systems and other media • Between water systems and other media • Between other media one to another if specified in the URS or similar specifications. B] "Air breaks" towards drain must be visible and at least 25 mm. c] Heat exchangers must be of the type double-plated heat exchanger or double tube-sheet tubular heat exchanger.	
5.11.12 **Deadlegs**	
Deadlegs: The incidence of "deadlegs" in process systems must be inimize to the extent possible to facilitate easy and effective cleaning and inimize the risk of microbial growth and other contamination of the product.	
Design: The design should aim at including as few deadlegs as possible. The deadlegs that cannot be avoided must be designed and constructed to be as small as possible. Deadlegs can result in a "hardest-to-clean area" which must be addressed in the cleaning validation.	

Specifications	Remarks

Area of application:

The requirement applies to process systems.

The requirement is however not relevant to:

- Systems with dry gasses.
- Dedicated systems with bacteriostatic media.
- Self-draining pipe branches in systems with pure steam.

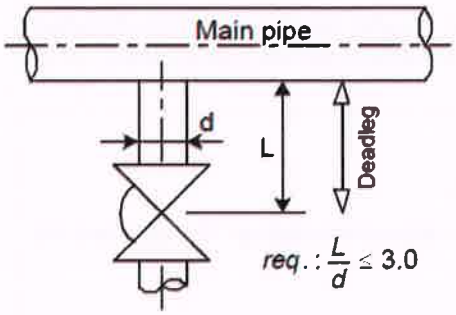
A] For deadlegs, one of the acceptance criteria listed below must be fulfilled.

As a primary rule, acceptance criterion 1 must be fulfilled.

Acceptance criterion 1

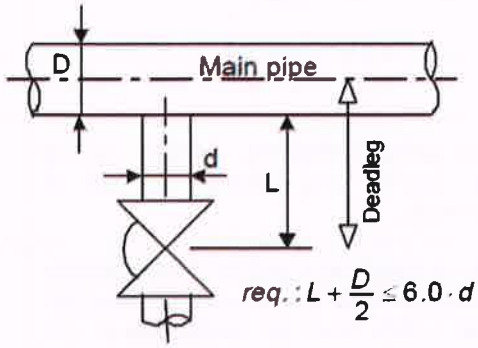
The length (L) of the branch measured from the outer surface of the main pipe must be smaller than or equal to 3.0 x the outer diameter (d) of the branch pipe.

I.e.: L/d ≤ 3.0



Acceptance criterion 2

The length (L) of the branch + the radius of the main pipe (half of the outer diameter, D/2) must be smaller than or equal to 6.0 x the outer diameter (d) of the branch pipe.
I.e.: (L+D/2)/d ≤ 6.0



Acceptance criterion 3

Specifications	Remarks
For diaphragm valves ≤ DN 10: The branch (deadleg) must be as small as possible (fulfilment of acceptance criterion 1 or 2 can't be expected).	
5.11.13 **Drain ability:**	
Drain ability: Process systems must be constructed so that they can be drained in connection with cleaning, maintenance and – if relevant – product or media changeover. Pipes must have slope. Components and instruments must be installed so that they are self-draining. For the lowest positioned points in the system ("local minima") a drainage arrangement must be built in, for example drain valve, clamp, pump connection, drain with "air break" or similar.	
Design: Short pipe sections should preferably be designed with a 2% slope and long pipe sections should be designed with a 1% slope. Slopes below 0.5% can only be accepted in exceptional cases.	
Specification:	
• All drains should be at the lowest point of the system for complete drainage.	
• The system shall have sufficient slope to drain out itself completely.	
• All utility pipes specifically pure steam/ water for injection/ condensate should have sufficient slope towards drain for complete emptying of the pipes	
• All drains must be equipped with an air-gap before connected to the drain system on site	
Area of application: The requirements apply to process systems. The requirements are however not relevant to systems with dry gases. Process support systems, utility systems and dedicated process systems with bacteriostatic media must all be drainable to allow easy and safe maintenance, but there is no requirement for a specific slope and the requirements are not subject to formal testing for these systems. **A]** Piping must have at least 0.5 % slope towards drainage points. There must be one or more points through which the piping can be emptied. **B]** The lowest positioned points in the system must all have a drainage possibility. Tanks and other process equipment, as well as instruments and components, must be designed and installed so the system can be drained. This includes that diaphragm valves on horizontal pipe sections must be angled in accordance with the valve manufacturer's instructions (if they cannot otherwise be drained).	
5.11.14 **Decontamination:**	
All surfaces in contact with media must be decontaminated (cleaned) before used in operation. This applies both to systems that are cleaned/CIP'ed as part of normal operations and systems that are not cleaned in operation. Decontamination should remove any contamination generated in connection with	

Specifications	Remarks
fabrication and installation of equipment, etc. The decontamination should not be confused with the cleaning that must be carried out in connection with the daily production. Decontamination does not necessarily ensure that the system is clean enough for production. Inversely, "normal" CIP does not necessarily ensure that the system is decontaminated. The systems must be decontaminated according to a specified procedure before being taken into use. The procedure can for example include successive rinses with NaOH-solutions, citric acid solutions and pure water. CIP procedures with NaOH-solution and HNO_3-solution can often also be used, but is must be assessed case-by-case. The procedure must be preapproved by the Process Owner or his representative. Systems for dry gasses can be decontaminated by blowing with pure process air or pure nitrogen instead of rinsing with liquids.	
Area of application The requirement applies to process systems. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests. A] Systems must be decontaminated before they are taken into use, according to a specified cleaning procedure. The cleaning procedure must be pre-approved by the customer appointed Project Manager and Project QA	
5.11.15 **Pipe marking**	
Piping must be clearly marked indicating what is carried in the pipes and direction of flow. The marking supports correct operation, maintenance, safety and environmental protection. A standard for pipe marking must be prepared covering the system. Typically, an existing standard for the plant/site is used, but a specific standard for the project/system may be agreed.	
Manual operation At certain points in process systems or process support systems wrong pipe marking may cause production errors (for example addition of the wrong media) or cross-contamination in connections with manual operation or other normal, operation-related actions. These critical locations must be specified in the URS (or another requirement or design document). Pipe marking must at these points be verified by qualification (Q). In all other places, pipe marking must be verified by commissioning ©.	
Area of application The requirement applies to all types of systems. A] Pipe installations must be provided with pipe markings according to the standard in effect on the site.	
5.11.16 **Insulation and cladding**	
Insulation and shielding: Insulation of pipes and tanks as well as other cladding and shielding arrangements are	

Specifications	Remarks
often necessary for safety, energy conservation, etc. Insulation and cladding on systems in classified clean rooms must have a sanitary finish.	
Cold/hot pipes Insulation and cladding of cold pipes and tanks in clean rooms must be sufficient to prevent condensation on the outer surface. Systems that are to be sterilised with pure steam must be sufficiently insulated for the required temperature to be achievable. Verification of insulation which is critical in consideration of sterilisation is done during OQ/PQ via identification and check of the coldest points.	
Insulation specifications Insulation/cladding for all systems is selected and dimensioned as part of the detailed design (if a local standard does not exist already) and must be specified in an insulation specification or similar document.	
Sanitary execution Assessment of what can be viewed as sanitary finish must be based on international, accepted standards for sanitary design, for example EHEDG Guidelines, 3-A Sanitary Standards or ASME's Bioprocessing Equipment [ASME BPE].	
Area of application The requirement applies to all types of systems. However, the requirement for sanitary finish only applies to those parts of the systems that are installed in clean rooms (room classes A, B and C). a] Insulation and cladding of pipe installations and tanks in classified clean rooms must be sanitary with regard to materials and execution/finish. Insulation of piping and tanks must be carried out with the insulation types and dimensions stated in the insulation specification for the system.	
5.12 Testing requirements	
5.12.1 FAT	
System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.	
Client must be given thirty (30) working days notice in advance of the testing date. The Vendor must ensure that the equipment to be tested conforms to the design requirements prior to notifying Client.	
FAT shall constitute part of the equipment qualification (Installation and Operational Qualification). They will be conducted at the premises of the Vendor in accordance with written procedures and protocols. The Vendor shall write these procedures and submit them to the client for written approval prior to carrying out the tests.	
The Vendor shall be required to undertake the testing and recording of all data in the test documents, witnessed by the client (and/or their representatives or agents).	
The equipment will be checked for its compliance with the specification. Testing shall include, but not be limited to:	

Specifications	Remarks
➢ Component check ➢ Documentation check ➢ Visual inspection ➢ Verification of drawings ➢ Dimensional check ➢ Functional checks. **Factory Acceptance Test procedures should include:-** ➢ Accuracy/ performance test shall be done on full integrated line instead of Separate single module.(If applicable) ➢ Description of item and function ➢ Checklist to show equipment properly installed, with services connected, equipment clean etc. ➢ Test equipment used and date of calibration	
In the event of the equipment failing to comply with any of the approved test procedures the Vendor shall, at their own expense, make such alterations and modifications to the equipment as are necessary, following an agreed Change Control Procedure. The test procedure(s) shall then be repeated to verify that the equipment meets the Design and Specification. The costs of any such repeat testing, including all expenses incurred by client Inspection Team, shall be borne by the Vendor.	
Only after satisfactory testing may the equipment be packed and dispatched. The approval of the Factory Acceptance Tests shall not constitute acceptance of the equipment.	
5.12.2 SAT	
The Vendor shall be responsible for checking the equipment installation, performing the start-up, and commissioning the equipment to agreed Site Acceptance Procedures. The Vendor shall write these procedures and submit them to Client for approval prior to carrying out the tests.	
Testing shall include inspection of the installation to check that the equipment has been installed correctly and is the equipment specified. It shall also demonstrate that the equipment will operate as intended throughout all anticipated operating ranges. If applicable the testing will include a repeat of the containment level tests as required during the FAT.	
It will be the Vendor's responsibility to ensure that the equipment conforms to the test procedures, and if a failure occurs, to make such modifications as may be necessary, and to re-test the equipment to prove that the equipment meets the requirements. Any modifications shall be subject to an agreed Change Control Procedure. All expenses of such re-testing shall be borne by the Vendor.	
➢ Site Acceptance Test Procedures should include:- ➢ Description of item and its function	

Specifications	Remarks
➢ Reference to manuals, guidelines, etc., required to carry out a test ➢ Test equipment used, and date of calibration ➢ Test objectives, methods, and acceptance criteria ➢ Test results ➢ Conclusions, including a clear statement of whether the item has been successfully qualified, or not.	
6.0 Technical Requirement	
6.1 **Basic Technical Requirement**	
6.1.1 The layout must be taken into account when determining the layouts of the units.	
6.1.2 A proposal of a possible installation layout should be added to the documentation.	
6.1.3 The manufacturer has to give the clear details on the total weight, capacity and dimension of the equipment.	
6.1.4 The heat given off by the unit must be stated (inside the room and through exhaust).	
6.1.5 The construction of the complete system should be described in the documentation in detail.	
6.2 **Level of Automation**	
6.2.1 The equipment should operate with minimum operator involvement. The equipment control panel must be provided with a Human machine interface based on English language with appropriate number of recipe of process parameters.	
6.2.2 The equipment should control automatically all critical parameters and detect failure mode automatically. Critical process parameters and failure modes are listed in the respective URS's.	
6.2.3 Human machine interface must be used to enter the process details, which should appear in the print out. Print out must provide results of all critical process parameters and failure alarms.	
7.0 Transport, Packaging and storage	
7.1 Delivery to site in presence of the Vendor's representative. Vendor's representative to ensure proper unloading and safe placement of the equipment with client's consent at site.	
7.2 Packaging and shipping of the equipment must take place only after written approval of the FAT. Release is given after inspection in the factory proving unobjectionable condition of the system.	
7.3 The vendor is responsible for installation. Installation to be coordinated with the client's commissioning supervisor.	

Specifications		Remarks
7.4	The freight and placement of equipment at site should be under the vendor's representative supervision. In this aspect, Vendor to depute an engineer who will be at site to oversee the unloading, placement of the equipment in the safe area within the client's place.	
7.5	Making necessary transport and lifting equipment available on site will be in equipment vendor scope.	
7.6	Protection against tilting and sliding must be provided.	
7.7	Transport packaging/identification Identification of transport packaging in clear lettering (indelible and water proof), font height min. 100 mm with following contents: • Manufacturer/vendor of system • Contact person principal • Contact person vendor	
7.8	The installation date agreed in the contract must be strictly followed.	
7.9	All Chargers for loading, unloading and placement in the required area will be borne by vendor	
8.0 Good Engineering Practices Requirements		
8.1	Equipment must be fabricated following all Good Engineering Practices. The vendor's Quality System must follow applicable national or international standards, such as ISO 9000. Internal quality procedures shall be available for the User's review.	
8.2	The Vendor shall provide a Quality and Project Plan as part of their proposal.	
8.3	The Vendor shall provide a Project Manager/Responsible person for the project to provide a single communication point with the User.	
8.4	Vendor must generate all applicable documents during all phases of equipment fabrication i.e. design, fabrication, testing and shipment as per applicable standards e.g. GAMP.	
8.5	All sensors, controllers, PLC, transmitters, indicators and any other controller or indicators to read, print or control any of the parameter, will have to be calibrated, traceable to national or international standard. Original calibration certificate along with traceability to be submitted by vendor in their IQ file.	
8.6	All material of construction should have test certificates.	
8.7	Vendor must generate and provide all specifications and test certificates of software used in the equipment control and/or monitoring system.	

Specifications	Remarks

9.0 Abbreviation

Terms	Abbrevation
AISI	American Iron and Steel Institute (US standardisation authority)
ASME	American Society of Mechanical Engineers (US standardisation authority)
CFR	Code of Federal Regulation (US)
CIP	Cleaning In Place
CR	Change Request
EDR	Enhanced Design Review
DN	Nominal Diameter
EHEDG	European Hygienic Engineering & Design Group
EN	European Norm
FDA	Food and Drug Administration (US)
GMP / cGMP	Good Manufacturing Practice / current GMP
HVAC	Heating, Ventilation and Air Conditioning
IRS	Installation Requirement Specification
ISPE	International Society for Pharmaceutical Engineering
P&ID	Piping and Instrumentation Diagram
UNS	Unified Numbering System (metallurgy)
URS	User Requirement Specification
USP	United States Pharmacopoeia
WPS	Welding Procedure Specification

Specifications	Remarks

10.0 Definitions

Term	Definition
C-marked requirements	Requirements that by requirement classification are assessed to be verified and documented by "Commissioning".
Media	Used here as a practical term for all materials/substances that are handled in the systems, i.e. materials / substances having direct or indirect contact with the product. It is typically liquids, but can also be gasses and solid substances.
Process Support Systems	Systems which directly support the process operations. These systems do not have contact with product or media in "process systems", but affect process operations, (such as heating, cooling or vacuum) or they deal with a side effect of the process, such as an air emission or a liquid waste [ISPE BPC].
Tag	A unique, unambiguous number identifying a technical installation location for instruments and equipment/components. The installation location is physically marked with the tag. Note: instruments typically also have an "ID No", which is independent of installation location (i.e. Tag ≠ ID No). ID No is used to ensure a traceable calibration.
Technical Discipline Specialist	A person from external company who has the necessary, documented skills, qualifications and/or experience to be able to make sound engineering and scientific assessments within the relevant technical area.
Utility systems	Systems that do not have contact with the product or media in "process systems". They are generally site- or building-wide systems that are not tailored to a specific process. For example plant steam and potable water [ISPE BPC].

11.0 References

Ref.	Title
1.	ASME – Bio-processing Equipment – 2004 (or later version) [ASME BPE]
2.	AWS D18.2 Guide to Weld Discoloration Levels on the Inside of Austenitic
3.	Stainless Steel Tube (American Welding Society) [AWS]
4.	Force Institute, Reference colour charts Report 94.34, chart 1 or 2 level C [Force]
5.	FDA – Guide to inspection of high purity water systems, July 1993 [FDA Water]
6.	ISPE Baseline Guide: Vol. 5, Commissioning and Qualification [ISPE C&Q]
7.	ICH Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients[ICH Q7]
8.	ISPE Baseline Guide: Vol. 1, Bulk Pharmaceutical Chemicals [ISPE BPC]
9.	FDA – Code of Federal Regulations, Title 21 [FDA 21 CFR]

	Specifications	Remarks
10.	EU Directives 2001/83/EC and 2001/82/EC	

Revision index

Revision	Date	Reason for revision
00	03-02-2014	First draft
01	13-02-2014	Updated as per comments given by HBL on 13-02-2014 by email

User Requirement Specifications
Lyophilizer

Block Code	Block	Identification #	Capacity	Qty [Nos]
F1	Viral vaccine Formulation - Rabies	F1-LYO 01	10 m^2	1
F1	Viral vaccine Formulation - Measles	F1-LYO 02	20 m^2	1

Table of Contents

1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective should be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

NNE Pharmaplan India Limited			
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Checked by			
Mr. Sridhar Babu K	Senior Process Engineer	K. Sridhar Babu	12/9/2014
Approved by			
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HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
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R. Suresh Babu	DGM (QC & QA)		15.09.14
Authorized by			
Kannan K. Ramachandran	CEO		15.09.14

2.0 EQUIPMENT DESCRIPTION

The Lyophilizer should be used to Lyophilise the Viral vaccine filled in half-stoppered ISO standard 2R & 4R vials. The fill volume for 2R vial-1ml and 4R vial-0.6 ml & 1.2ml (10% overage will be considered over the fill volume).

S. No.	Identification no.	Capacity	Vial Size
1.	F1-LYO 01	10 m^2	2R
2.	F1-LYO 02	20 m^2	4R

The Lyophilizer should be of single door type for loading and unloading from the same Class A/B room. The Pizza Type door should opening in the aseptic area for loading / unloading of vials. The vial loading and unloading should be done with manual LUS using transfer carts/frames.

Stoppering conditions should be done in the presence of vacuum/nitrogen gas.

Whereas at the back side of the chamber opening in the technical area should be the full body swing door for maintenance access. Accordingly, the condenser should be placed on one side of the chamber.

As per the equipment location layout the Lyophilizer should be configured with condenser and refrigeration unit with all accessories.

The machine should consist of following parts in order to run operation smoothly

S. No.	Description	Purpose
1	Chamber with the shelves	For keeping the vials for lyophilization equipped with pizza door in the sterile room for loading/unloading of vials
2	Condenser with the cooling coil	For trapping the vapour on the coil from the chamber
3	Refrigeration system	For cooling the product as per the product specification
4	Heating system	For heating the product as per the product specification
5	Vacuum System	For creating the desired vacuum as per the product requirement
6	Hydraulic system	For movement of the shelf for auto stoppering of the lyophilized vials inside the chamber
7	Silicon oil circulating system	For transferring the heat by convection and conduction by circulation of silicon oil
8	CIP system	For CIP of complete system
9	SIP system	For SIP of the complete system
10	Loading and Unloading System ***(Not in Lyophilizer vendor scope)***	For loading the vials in to the chamber shelf and unloading the vials from the shelf for sealing.
11	Aeration system with provision for filter integrity test	To validate the filter integrity
12	PLC with SCADA	For process control and data acquisition

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of any deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non-compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI-120310-IRS-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-06

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1. **Filled and half stoppered vials**: Filled and half stoppered vials will be collected in collection trays and loaded into the mobile LAF cart which is minimum 900mm from the floor level.	
3.1.2. Mobile LAF cart will be transferred from filling line to the Lyophilizer loading to load the vials in to the chamber.	
3.1.3. **Process air:** Sterile Filtered air will be used to purge the chamber and condenser during vacuum break. Sterile Filtered air is also used for drying the chamber and condenser after the SIP / CIP cycle.	
3.2 Brief Process Steps	
The Lyophilizer should perform the following process step:	
3.2.1 Automatic leak test of the chamber along with shelves.	
3.2.2 CIP of the chamber and condenser.	
3.2.3 SIP of the chamber and condenser.	
3.2.4 Lyophilisation process.	
3.2.5 Provision for Partial aeration of the chamber with sterile nitrogen gas	
3.2.6 Stoppering of vials under vacuum/Sterile Nitrogen gas	
3.2.7 Vacuum break.	
3.2.8 Aeration of the chamber to atmospheric pressure using sterile filtered air.	
3.2.9 De-icing.	
3.3 Output & Discharging method	
3.3.1 Full-stoppered vials with lyophilized vaccine: Loading/Unloading trays with full stoppered vials are transferred horizontally back into mobile LAF cart and it will be transferred from Lyophiliser unloading area to the sealing machine.	
3.3.2 Full stoppered vials are transferred on trays from mobile LAF cart into the loading section of the vial sealing machine.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
4.1.1 **F1- LYO 01:-** The Lyophilizer should be capable of lyophilizing not less than 40,000 vials of DIN **ISO 8362-1: 1989€ 2R (Tubular)** each vial containing 1ml of product.	
4.1.2 **F1- LYO 02:-** The Lyophilizer should be capable of lyophilizing not less than 80,000 vials of DIN **ISO 8362-1: 1989€ 4R (Tubular)** each vial containing 0.6ml&1.2ml of product.	
4.1.3 a. **F1- LYO 01 :** Minimum Ice condenser capacity should be 150 kg or its nearest standard with performance of 120 kg/24 hour b. **F1- LYO 02 :** Minimum Ice condenser capacity should be 300 kg or its nearest standard with performance of 200 kg/24 hour	

Specifications	Remarks

4.2 Standard batch size / process time

Identification #	Batch size vials/ batch	Vial size	Lyophilisation process time	Volume per vial	Remarks
F1-LYO-01	40000	2R	48Hrs	1 ml	
F1-LYO-02	80000	4R	52Hrs	0.6 ml	
				1.2 ml	

4.2.1 Vendor should provide the following requirement on the basis of batch size of **F1- LYO 01 & F1- LYO 02**

4.2.1.1 Frame size and numbers of vials/frame

4.2.1.2 Frames/ Load

4.2.1.3 Frames / shelf

4.2.2 Frames: The frame size need to be designed based on the quality of the vials, homogeneity, tolerance for robust loading and unloading of vials. The arrangement of the vials in the frame should be row shape.

Note: Vendor should supply frames and trays capable to accommodate the following capacities

i. **F1-LYO 01:** Frames for 40000 vials / batch of 2R size and trays to accommodate 1/3rd of the required capacity.

ii. **F1 LYO 02:** Frames for 80000 vials / batch of 4R size and trays to accommodate 1/3rd of the required capacity.

Vendor to provide the GA drawing of the frames and trays along with the technical bid. The quantity of the frames should be equivalent to 1 batch.

4.3 Change Over Time (if applicable)

Not applicable

4.4 Other Productivity Requirement

4.4.1 The following sequence to be accomplished fully automatic within eight hours:

- De-icing
- CIP
- SIP
- Drying in place
- Leak test
- Re-cooling
- Filter integrity test

5.0 CONTAINMENT

Not applicable

Specifications	Remarks
6.0 GMP REQUIREMENTS	
6.1 Process Control	
6.1.1 Shelf temperature from ambient should reach – 55℃ in 60 minutes time under no load condition.	
6.1.2 Refrigerant circuit must work in over pressure also when condenser is at -70℃	
6.1.3 Shelf temperature from - 55°C up to + 40°C(standard deviation among all shelves +/- 2°C)	
6.1.4 During process cycle, the Lyophilizer should achieve the following range of temperatures; a) Chamber temp: -55 ℃ b) Condenser temp: -70 ℃	
6.1.5 Automatic determination of end of drying by pressure increase test is required	
6.1 Failure mode detection	
6.2.1 Equipment should be capable to detect the following failure, notify the operator with alarm[audio & visual] and shutdown the process.	
6.1.1.1 Emergency stop activated	
6.1.1.2 The steam temperature during the SIP hold time below the set limit (only alarm required)	
6.1.1.3 The vacuum pump stop during the process (only alarm required)	
6.1.1.4 The compressor stop during the process (only alarm required)	
6.1.1.5 The silicone oil circulating pump stop during the process (only alarm required)	
6.1.1.6 The Hydraulic pump stop during the process (only alarm required)	
6.1.1.7 Purging stop during the process (only alarm required)	
6.1.1.8 Electrical Heater (Silicone oil Heating system) failure during the process (only alarm required)	
6.1.1.9 Water ring vacuum pump stop during the process (only alarm required)	
6.1.1.10 Failure in data communication during the process (only alarm required)	
6.1.1.11 The hydraulic movement of the shelf should be stopped when the generated pressure in the system goes beyond the set limit. (alarm & shutdown required)	
6.1.2 **Equipment should be capable to detect the following failure, notify the operator for procedural control**	
6.1.2.1 The compressed air / Nitrogen pressure below the set value.	
6.1.2.2 The purified water and WFI pressure below the set value during the CIP cycle.	
6.1.2.3 The condenser cooling failures during the lyophilisation cycle.	
6.1.2.4 The set vacuum level not achieved.	
6.1.2.5 Test failure [not limited to i.e. chamber leak test failure, pressure rise test, water load test.]	
6.2 In –Process control	
Not Applicable	

Specifications	Remarks

6.3 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Operation range	Desired Least Count	Extent of Instrumentation				Remarks
				Indication	Alarm	Control	Recording	
Temperature	For controlling/ monitoring the shelf temperature	(- 60) ℃ to (+ 60 ℃)	0.1 ℃	Y	Y	Y	Y	
Temperature	For controlling/ monitoring the condenser temperature	(- 90) ℃	0.1 ℃	Y	Y	Y	Y	
Temperature	For controlling/ monitoring the Chamber drain temperature during SIP	0-150 ℃	0.1 ℃	Y	Y	Y	Y	
Temperature	For controlling/ monitoring the condenser drain temperature during SIP	0-150 ℃	0.1 ℃	Y	Y	Y	Y	
Temperature	For controlling/ monitoring the vent filter temperature during SIP	0-150 ℃	0.1 ℃	Y	Y	Y	Y	
Pressure	For controlling/ monitoring the lyophilizer chamber pressure	1 bar (a) to 2.5 bar (a)	1 mbar	Y	Y	Y	Y	
Pressure	For monitoring/ controlling the pressure across the sterilizing grade vacuum break filter	1 bar (a) to 8.0 bar (a)	0.01 bar	Y	Y	Y	N	
Pressure	For monitoring the main compressed air line pressure for pneumatic control	1 bar (a) to 8.0 bar (a)	0.1 bar	Y	Y	Y	N	
Pressure	Hydraulic Pressure	1 bar (a) to 160 bar (a)	0.1 bar	Y	Y	Y	N	
Vacuum	Chamber Vacuum	1 µ bar (a)	--	Y	Y	Y	Y	

Note:- Y *Required,* **N** *Not required*

6.4 Batch data display and record

Refer Installation Requirement Specification

	Specifications	Remarks
6.5	**GMP requirements (Others)**	
6.6.1	The stoppering system of the Lyophilizer should not generate particle or affect the sterility of the system.	
6.6.2	The installation of piping and components in the technical area must be as such that all the pipes and components are easily reachable for maintenance.	
6.6.3	Separate control cabinets that are not integrated into the equipment should be located outside the clean room environment in the technical area, refer attached layout. The necessary length of connecting cables must be considered.	
6.6	**Specific requirements**	
6.6.1	CE certification for the equipment is mandatory.	
6.6.2	Online Automatic integrity testing of vent filters should be provided.	
6.6.3	**Electric Motors**	
6.6.3.1	Possible leakage currents from the frequency transmitters or upstream filters must not influence the automation networks or analogous measuring signals respectively.	
6.6.3.2	All electrical components like motors must be controlled by control cabinets.	
6.6.3.3	Motors must be protected by safety switches.	
6.6.3.4	In order to avoid high start-up currents of large actuators (as from 7.5 kW) without frequency transmitter, suitable measures (soft starter) must be projected.	
6.6.4	**Chamber:**	
6.6.4.1	The chamber must be pressure rated to withstand conditions up to 130°C and 2.7 bar (a) found during sterilization.	
6.6.4.2	All safety features relevant for pressure vessels must be provided as stipulated in the pressure vessel and safety standards.	
6.6.4.3	Special attention must be given to the safety valves being tight also in vacuum.	
6.6.4.4	Chamber bottom, all ports and flanges welded to the chamber and all interface lines and dead legs must be sloped with minimum 2% for proper drainage.	
6.6.4.5	All internal corners must be rounded for easy cleaning (r > 20 mm where possible).	
6.6.4.6	All area on top of the chamber that must be accessed for maintenance or calibration purpose must be reinforced.	
6.6.4.7	A bellow must be provided to cover the hydraulic cylinder shaft of the shelf movement in order to maintain sterility of the unit. A continuous leak control must be provided to assure no leakage of the bellow during SIP. The system design must facilitate CIP and SIP cycles. Sterility must be maintained during the full cycle.	
6.6.4.8	The diaphragm sampling valve should be provided at the chamber drain line	
6.6.4.9	The chamber should have the following ports and connection but not limited to : • Vacuum measuring probes • Pressure transmitter • Process Air/ nitrogen gas inlet • Connection to condenser • Validation ports – 2No.s to be provided (integral to the entire machine).	

Specifications	Remarks
• CIP/ SIP inlet • Overpressure safety valves • Sight glass with illumination to the chamber and condenser. (1 no in technical area and 1 in the loading side(Cleanroom)) • Chamber Drain • Refrigerant inlets/ outlets • Cooling jacket inlet /outlet • Cooling jacket safety valve	
6.6.4.10 The chamber must be equipped with a system (e.g. sieve) to prevent glass of broken vials entering the chamber drain or other piped outlets. The sieve must be easily accessible for removal of trapped particles and cleaning.	
6.6.4.11 The chamber have to be designed for automated CIP/SIP cycles	
6.6.4.12 Suitable liquid-ring pump should be in place to evacuate the CIP solution from the chambers after CIP	
6.6.4.13 All Valves should be of sanitary type for CIP and WFI which is directly connected to chamber.	
6.6.5 **Ice condenser:**	
6.6.5.1 The distance between the ice condenser and the drying chamber should be kept to a minimum. Preferably the condenser is integrated into the main chamber of the freeze dryer.	
6.6.5.2 Depending on the configuration of chamber and condenser the vendor is asked to describe the design of the isolation valve between chamber and condenser.	
6.6.5.3 Direct visual contact between condenser and product should be avoided (radiation influences) for example by the use of a large poppet valve plate.	
6.6.5.4 The condenser must be pressure rated to withstand conditions up to 130°C and 2.7 bar (a) found during sterilization.	
6.6.5.5 The condenser have to be designed for automated CIP/SIP cycles	
6.6.5.6 All safety features relevant for pressure vessels must be provided as stipulated in the pressure vessel and safety standards	
6.6.5.7 Special attention must be given to the safety valves being tight also in vacuum.	
6.6.5.8 Condenser bottom, all ports and flanges welded to the chamber and all interface lines and dead legs must be sloped with minimum 2% for proper drainage.	
6.6.5.9 All internal corners must be rounded for easy cleaning (r > 20 mm where possible).	
6.6.5.10 Design should be based on maximum ice thickness on condenser tubes.	
6.6.5.11 The condenser chamber, refrigerant cooling coil and jacket must be provided with safety devices stipulated in the pressure vessel and safety standards.	
6.6.5.12 The insulation should be complete to avoid icing in the technical area. Catchment tray to be provided to collect the condensed ice and further this catchment should lead to the main drain point in the room.	
6.6.5.13 The ice condenser should have the following ports and connection but not limited to: • Pressure transmitter for overpressure	

Specifications	Remarks
• Air/ inert gas inlet • Vacuum system • Main vacuum valve to the chamber • Spare flange • Validation flange • CIP/ SIP inlets • Overpressure safety valves • Drain • Refrigerant inlets/ outlets	
6.6.5.14 The ice condenser must be equipped with an automatic aeration independent from the chamber	
6.6.5.15 A bellow must be provided to cover the hydraulic cylinder shaft of the valve in order to maintain sterility of the unit. A continuous leak control must be provided to assure no leakage of the bellow during SIP. The system design must facilitate CIP and SIP cycles. Sterility must be maintained during the full cycle.	
6.6.5.16 Cycle life of bellow must be not less than 10^5 cycles.	
6.6.5.17 The condenser must be equipped with a system (e.g. sieve) to prevent glass of broken vials entering the chamber drain or other piped outlets. The sieve must be easily accessible for removal of trapped particles.	
6.6.5.18 The vendor should provide the detail nozzle schedule of the chamber and condenser in the documentation.	
6.6.5.19 It has to be assured that fallen vials cannot reach the condensers under all conditions. The used precaution should be described.	
6.6.6 **Chamber Door:**	
6.6.6.1 Pizza door [Vertical sliding] should be provided for vials loading with smooth integration of the stainless front cover, there should be no parts extending into the clean room disturbing the laminar air flow.	
6.6.6.2 Manual hinged full size door for maintenance access to chamber, shelves and condenser. Opening at least 100°. The closing bolts should be operated automatically.	
6.6.6.3 The chamber door must be foreseen with a door contact to detect the position of door.	
6.6.6.4 Appropriate design should be provided for chamber door cooling.	
6.6.6.5 Door locking switch: Only individually coded safety switches must be used.	
6.6.6.6 Door contacts must have an interlock with the venting valve to make sure no air & N2 can enter the chamber with the door open.	
6.6.6.7 Door gaskets must be able to withstand CIP/ SIP. The sealing of the door must be designed in a way that no condensate or CIP water remains between the door and the chamber.	
6.6.6.8 The door operation (opening and closing) should be manual and sealing will be automatic with door locking indication in the PLC.	
6.6.6.9 The door sealing must operate without any additional lubricant.	
6.6.6.10 The replacement of any door sealing must be possible without disassembling of any other parts or components.	

Specifications	Remarks
6.6.6.11 The door must be auto locked if the pressure in the chamber goes above atmospheric pressure.	
6.6.6.12 The service area should be provided with the full swing door.	
6.6.6.13 The panelling of the equipment should reach the suspended ceiling. The cladding panel should be constructed to allow easy removal for inspection and maintenance.	
6.6.6.14 MOC of gasket should be USFDA approved.	
6.6.7 **Loading/Unloading**	
6.6.7.1 Mobile LAF cart will be used for loading and unloading of vials from the lyophilizer. Loading & unloading of vials will be manual.	
6.6.7.2 Height of the Loading and unloading should not be less than ~900 ±30 mm from the floor level.	
6.6.7.3 Vials have to be pulled or pushed manually frame by frame from/to the shelf for unloading/loading	
6.6.7.4 Mechanical changes or adjustments for format change must be avoided.	
6.6.7.5 For transportation of vials from filling line to lyophilizer loading and from lyophilizer unloading side to loading side of sealing machine will be done by Mobile LAF.	
6.6.8 **Shelves**	
6.6.8.1 Shelf distance has to be optimized for given vials (half stoppered). clearance between the two shelf should be not less than 70mm.	
6.6.8.2 Roughness of top side of all shelves should have an Ra value < 0.8 µm	
6.6.8.3 Bottom side of all shelves should be designed suitably to prevent sticking of stoppers.	
6.6.8.4 The planarity of the shelves must not to exceed 1.0 mm over the whole shelf.	
6.6.8.5 A radiation shelf must be foreseen between load frame first shelf to ensure that drying conditions on all shelves are the same.	
6.6.8.6 One product probe per shelf for product temperature and eutectic point monitoring to be provided.	
6.6.8.7 Special arrangements to be provided to secure the temperature probe during stoppering/moving the shelves.	
6.6.8.8 Shelf guiding and positioning in all directions must be reproducibly accurate to ensure docking of the loading and un-loading process So as to avoid flipping vials or damaged vials	
6.6.8.9 Fixed guide stoppers should be provided within the shelves to prevent high friction force during loading and unloading (manual mode) of the vials.	
6.6.8.10 The flexible tubes must be free of tension during upwards and downwards movement.	
6.6.8.11 The connections of the cooling / heating media flexible pipes to the shelves must be welded (preferred solution) or with leak-proof coupling.	
6.6.8.12 All quality tests to ensure robust design should be carried out post fabrication and documented.	

Specifications	Remarks
6.6.8.13 It has to be sure, that no vials will fall from the sides of the shelves. Therefore the shelves should be executed with a border system on the sides to ensure coherent lyophilization conditions even on the shelf edges	
6.6.8.14 The collapsing (and levelling after CIP/SIP) of shelves should be performed automatically. The construction should be described in the documentation.	
6.6.8.15 The connection of heating/cooling media to the shelves should be leak proof.	
6.6.8.16 In addition the position of each shelf must be mechanically adjustable (to ensure minimum tolerances concerning constant loading level for each shelf).	
6.6.8.17 The shelf must be level and the constructed to tolerance of ± 0.5mm/metre.	
6.6.8.18 Each shelf should have raised SS edge on the rear and on the left & right to ensure the location of the vials.	
6.6.8.19 Control of shelf movement should be provided from both sides (Clean room and technical area).	
6.6.8.20 Emergency stop button for shelf movement should be provided on both sides (Clean room and technical area).	
6.6.9 **Hydraulic System for Shelves**	
6.6.9.1 The positioning must be accurate enough to harmonize with the transfer cart / frames.	
6.6.9.2 Hydraulic drive for the shelves to allow loading at constant level and closing of vials.	
6.6.9.3 The shelf lifting mechanism should not pull any contaminants into the chamber.	
6.6.9.4 The bellow should be removable from the chamber without removing the complete piston.	
6.6.9.5 The effective stoppering function required.	
6.6.9.6 Shelves and the hydraulic cylinder must be designed in a way to prevent the need for spacers even if only one shelf is loaded.	
6.6.9.7 Shelves must be kept compressed after stoppering of the product until the pressure in the chamber has reached a value (adjustable).	
6.6.9.8 All the shelves should be pressure tested at 20% higher than the design pressure.	
6.6.9.9 A leak tight bellow must be provided to cover the hydraulic cylinder shaft in order to maintain the sterility of the unit.	
6.6.9.10 The hydraulic pump should be provided with high pressure interlocking	
6.6.9.11 Hydraulic system should be operated by both the side (sterile, Non sterile).	
6.6.9.12 Full stoppering pressure should be adjustable from 0-70KN/m^2	
6.6.9.13 Stoppering speed should be around 4mm/sec	
6.6.9.14 Shelves need to be positioned using hydraulic system for loading and unloading of vials.	
6.6.10 **Heating and Cooling for Shelves**	
6.6.10.1 The heating and cooling system must operate automatically.	

Specifications	Remarks
6.6.10.2 The preferred heat transfer medium in the secondary loop is silicon oil.	
6.6.10.3 A backup pump system must be provided, which is automatically activated when the primary system fails.	
6.6.10.4 An expansion vessel (with filter cartridge) with pressure indication should be provided.	
6.6.10.5 Each shelf must be separately fed with cooling / heating medium.	
6.6.10.6 Pt 100 (min. 3 wired) temperature probes placed in stainless steel tubes both at the inlet and the outlet of the shelf manifold should be provided. (1 Pt 100 used for cycle control, 1 for measurement)	
6.6.10.7 Distribution of heating and cooling media should be uniform throughout the shelves (without any dead spaces) so that proper and uniform freeze drying of the product can be achieved and temp difference of the shelves must be ±1 °C.	
6.6.11 **Primary Cooling System**	
6.6.11.1 The cooling system should consist of two independent refrigeration circuits. - The first circuit works with a heat exchanger in the silicon oil circulation system for shelf cooling. The second circuit works by direct expansion on the tubes of the ice condenser.	
6.6.11.2 The cooling circuit must be built in that way that all compressors can be used for the cooling of the shelves (initial freezing) and that during drying one compressor can be used for the shelves and the others for the cooling of the condenser.	
6.6.11.3 Compressors should be two stages.	
6.6.11.4 Redundancy for compressor, vacuum pump, to be in place so that if one of the above equipment fails, cycle must complete safely and automatic switching off should be considered.	
6.6.11.5 The following safety devices have to be provided but not limited to: • A pressure valve to avoid overload during starting: start pressure regulation • Hand valves in the upstream and downstream of the compressors. • Thermal circuit breaker • Thermistors in the motor coils with control unit. • High pressure lubrication system with a gear pump. • Auxiliary cooling system by expansion of refrigerant through the motor including: temperature switch with bulb on the discharge line, solenoid valve, expansion system, bypass line and electrical control. • Differential oil pressure switch • High pressure switch. • Pump down must be done during standby of the compressor When the pressure is low enough the compressor must stop running • Crankcase heater to avoid any refrigerant condensation when the compressor is switched off. • Check-valve on the discharge line. • Double safety valves for each compressor unit.	
6.6.11.6 Only HFCs according to Montreal protocol are permitted as refrigerants. Vendor to specify the type of refrigerants used.	

Specifications	Remarks
6.6.11.7 Temperature measurements at the inlet and outlet of the cooling water. Measurements must be visible on SCADA.	
6.6.11.8 Pressure switch at low, intermediate and high pressure side of the compressors.	
6.6.11.9 Intermediate pressure side must always be > 1 bar (a).	
6.6.11.10 Pressure transmitters in refrigerant circuit at outlet of the ice condenser and silicon oil heat exchanger of the cooling system. Measurements must be visible on SCADA.	
6.6.11.11 Oil separator (after compressor) and liquid separator (before compressor) must be provided.	
6.6.11.12 Possibility to open oil separator for cleaning.	
6.6.11.13 A separate connection for filling the compressors with cooling liquid must be provided.	
6.6.11.14 Drainable trays to collect the condensate below the compressors have to be provided.	
6.6.11.15 All components reachable to perform maintenance	
6.6.11.16 During a WIT, the condenser needs to be cooled to gain time during the leak test if this follows the WIT.	
6.6.11.17 If leak test fails, option to be provided in the lyophiliser to abort the cycle or restart.	
6.6.12 **Vacuum System**	
6.6.12.1 Vibration dampers need to be foreseen to minimize effect of vibration of pumps to the surrounding operations.	
6.6.12.2 The rotary vane vacuum pumps should operate with gas ballast in order to avoid water vapour condensation and to force oil diffusion to the exhaust.	
6.6.12.3 Oil sealed primary pumps are used. A system should be provided to avoid oil diffusion into the condenser.	
6.6.12.4 As an alternative the vendor should propose a suitable oil free system (dry pumps)	
6.6.12.5 A safety valve between the condenser and the vacuum system must be provided. In case of power failure this valve has to close immediately and automatically.	
6.6.12.6 A vacuum system capable of generating a vacuum of up to: • 0.005 mbar(a) in the chamber • 0.003 mbar(a) at pump head	
6.6.12.7 The evacuation time of the system from atmospheric pressure to: • 0.1 mbar(a) should take less than 40 min	
6.6.12.8 The control system incorporates the following • 1 pressure transmitters (MKS) installed on the drying chamber.	
6.6.12.9 High pressure alarms Pmax-x (stop of heating) and Pmax (refreezing of shelves) have to be split up in primary and secondary drying.	
6.6.12.10 Chamber vacuum should be maintained after the completion of cycle (with Alarm)	

Specifications		Remarks
	.Vacuum should be released only on human intervention.	
6.6.12.11	Choice of aeration with either N2 or process air: selectable by software and recipe driven	
6.6.13	**Ergonomic requirements**	
6.6.13.1	Equipment which must be calibrated should be installed for easy access from floor level	
6.6.13.2	To improve the accessibility pedestals and stairs to be provided.	
6.6.13.3	Accessibility of all buttons, switches and components for operator handling is required.	
6.6.13.4	The specified equipment must be designed and executed without sharp hooks and borders to avoid injuries.	
6.6.14	**Performance requirement**	
6.6.14.1	Chamber: Maximum leak rate of < 0,01 mbar * l *s-1 in the range of 0.01mbar till 0.1 mbar at condenser temperature of -40 Deg. C	
6.6.14.2	Condenser: Maximum leak rate of < 0. 01 mbar l/s starting with initial vacuum at < 0, 01 mbar.	
6.6.14.3	A leakage rate between drying chamber and the ice condenser of less than $1*10^{-7}$mbar*l*s-1 should be guaranteed. The valve between the product chamber and the condenser chamber must have stable positioning and be absolutely tight in both directions against atmospheric pressure. A pressure rise test with an open and with a closed valve (atmospheric pressure in the condenser chamber) must be performed.	
6.6.14.4	Water Load Test: - A purified water load test should be performed. This test should evaluate the systems sublimation rate capacity and ice loading pattern on the condenser. - Purified water will be put upon the full loaded surface area of each shelf utilizing trays. Each tray should be equally filled such that the total load is equal to the specified ice capacity.	
6.6.14.5	Minimum ramping velocity with full chamber should be of 1 ℃ /min.	
6.6.14.6	Temperature difference between manifold inlet and outlet should be ±1 ℃ in a steady state with load.	
6.6.15	**General Design Requirements**	
6.6.15.1	The max. Length of the flanges and ports must be designed so that these flanges and ports are cleanable and sterilizable. Dead ends <1.5d where possible.	
6.6.15.2	All blind flanges must be able to withstand the full vacuum as well as the sterilization pressure.	
6.6.15.3	Moving parts which are going outside of the sterile area should be foreseen with a leak-tight bellow (with possibility to verify.) Air from bellow is blown in technical area.	
6.6.15.4	Critical process valves (min. requirement: process water valves, media lines, bottom valves, pressure release valves, etc.) must be equipped with end position switches.	
6.6.15.5	Activation of the emergency stop button or opening of the protective door (if available) leads to immediate stop of all outputs via the safety circuit.	

Specifications	Remarks
6.6.15.6 Activation of the emergency stop button or opening of the protective door (if available) leads to immediate stop of the valve clusters.	
6.6.15.7 Installation of equipment with refrigerants has to be done by a certified cooling technician. Before starting the works, a copy of the certificate has to be delivered.	
6.6.15.8 An over-temperature switch has to be installed in the control circuit of the heating relay	
6.6.15.9 All lines and equipment surfaces which represent a danger to operators and maintenance personnel with regard to freezing or burns should be adequately insulated.	
6.6.15.10 A central vacuum valve between the condenser and the vacuum system must be provided. In case of power failure this valve has to close immediately and automatically.	
6.6.15.11 In case of power failure the valve between the drying chamber and ice condenser should remain in previous position before power failure.	
6.6.15.12 During the SIP cycle after power failure recovery, another new SIP cycle should restart from the beginning (if temperature drops below the set value).	
6.6.15.13 During the CIP Cycle, De-Icing Cycle, and lyophilization cycle after power failure recovery the remaining sequence of the cycle should restart from the stop point.	
6.6.15.14 Provision to provide to connect the control system to Centralised UPS system of the facility. The UPS power will be used for all sensors, Data printer, recorder , PLC controls, Visualization inside the chamber When electricity power resumes, the system should start automatically with recipe loaded where the power failure occurred. The pre-requisite for automatic continuation is that set parameters are still with valid ranges. All the major components and processes must start automatically within 3 minutes.	
6.6.15.15 All hygienic lines, WFI, CIP water and pure steam must be orbital welded. All welded lines in contact with WFI, CIP water or clean steam must be inspected by endoscope (10% of welds). Inspection certificate with photographs with P&ID tags to be provided.	
6.6.15.16 Vendor should provide the effective design for CIP to minimize the water consumption.	
6.6.16 **Cleaning and Sterilisation requirement**	
6.6.16.1 Automatic CIP and SIP	
6.6.16.2 The Clean in Place system should include manifolds, nozzles/ spray ball and sanitary valves to allow the CIP media to be sprayed onto product chamber, condenser and shelf surfaces	
6.6.16.3 Number of spray ball, position, location and height of the spray ball should be provided by the vendor	
6.6.16.4 Effective cleaning of nozzles should be possible. Replacement of nozzles should be possible without disturbing the position and spray direction.	
6.6.16.5 CIP should be once through with available utilities mentioned in the section 7.2 of this URS	
6.6.16.6 The CIP cycles will be recipe driven and fully automated with temperature, flow rate and volume control.	

Specifications	Remarks
6.6.16.7 The CIP must ensure that 100% of the chamber and condenser with all process pipings are cleaned. Suitable and sufficient spray nozzles for complete impact cleaning must be provided.	
6.6.16.8 The drying chamber, the shelves, the ice condenser and all connecting lines and all the ports on the chamber have to be cleaned in place.	
6.6.16.9 All valves in CIP lines and lines to be CIP'ed must be sanitary valves.	
6.6.16.10 Vendor to specify spray pressure, spray time, selection sequence of the spraying nozzle along with their spray time	
6.6.16.11 SIP consists of the following steps: • Vacuum to evacuate all the air • Heat up • Sterilization • Cooling and drying	
6.6.16.12 The respective pressures, temperature and durations should be defined as parameters in the recipe. 6 log reductions should be achieved during SIP on all surfaces within the chamber, condenser, and CIP system.	
6.6.16.13 The temperature difference across and between shelves during the sterilization hold period must be less than 1 deg C.	
6.6.16.14 The sterilization cycle must be controlled by the temperature at the coldest spot and the pressure in the chamber.	
6.6.16.15 SIP cycle must be equipped with automatic actuated control valves and steam traps.	
6.6.16.16 The supplier of the Lyophilizer should ensure to cool down the condensate < 60ºC.	
6.6.16.17 Adequate space should be provided for manual cleaning and inspection of shelves and chamber area from the access door on the mechanical side of operations. Total opening of the door should be 150deg angle.	
6.6.16.18 The configuration of any flanges and ports must ensure that all internal surfaces are covered by the CIP system and will reach and maintain sterilization conditions during the sterilization cycle.	
6.6.16.19 The SIP cycle sterilization hold time should reset as the drain probe temperature comes below 121 ^{0}C and recounting of the time should start after achieving the set sterilization temperature. If the door is closed incorrectly, CIP/SIP should not start.	
6.6.16.20 For CIP / SIP of the Lyophilizer the shelf should have a collapsible angle of 5 degree approximate to avoid water or condensate on the shelf.	
6.6.17 **Maintenance requirement**	
6.6.17.1 Lubricating points: All lubricating points must be registered, shown and clearly labelled in an overall plan. Inaccessible lubricating points must be made accessible by installing corresponding lines without opening the protective door. It must be guaranteed by suitable measures that oils or lubricants do not reach the product. The lubricant type applied must be registered. Oils and lubricants applied must be approved by USFDA. A corresponding certificate must be supplied.	
6.6.17.2 Testing means lists The suppliers must provide the testing means lists electronically as tables. Testing means include all process and quality relevant measuring points, e. g.	

	Specifications	Remarks
	temperature, pressure, LF, flow etc. Testing means must be classified in terms of Biotechnology or technical relevance. In advance, the measuring points must be agreed upon with the principal. For measuring points the following must be indicated: measuring range, calibration range, working range, set-point, accuracy class, recommended calibration frequency.	
6.6.17.3	Access to testing means: The testing means must be easily accessible and assembled under due consideration of an easy and quick recalibration. Necessary auxiliary energies (220 V, compressed air) must be available in the proximity of the measuring points.	
6.6.18	**Interface to other systems**	
6.6.18.1	Interface: The required interconnection to other systems takes place by means of potential free contacts. Besides those mentioned in this URS, 5 additional potential free contacts must be provided for further occupation (e. g. control of a vapour extractor.	
6.6.18.2	Collective Alarm: In order to centrally visualize the general system condition, a collective alarm signal should be provided on a potential free contact.	
6.6.18.3	Interfaces to on site utility supply systems: The onsite utilities are specified in attached utility spec.	
6.6.18.4	If the specified equipment is connected or integrated into on site partition walls or ceiling panels dimensions and locations for necessary cut-outs must be stated in the equipment layout drawings.	
6.6.18.5	Parts of the specified equipment must not be attached to cleanroom ceiling panels	
6.6.18.6	Interface with building and building services such as process utilities	
6.6.19	**Level of Automation**	
6.6.19.1	The freeze drying process operates without operator's assistance. Operator selects or downloads recipes and starts the freeze dry cycle. All operations should be controlled by PLC-controller and the SCADA-system with a variety of different recipes for different products. Industrial Computer system and Printer should be provided.	
6.6.19.2	Data loss is not admissible.	
6.6.19.3	Fail safe position: In case of auxiliary energy failure (electric or pneumatic) the armatures and actors must run into defined fail safe position so that no hazard is caused to persons and products.	
6.6.19.4	Energy efficiency class: All electric motors must at least comply with the current requirements of the EC energy efficiency class (EFF2).	
6.6.19.5	Actors: In case of error or failure of the field bus communication the actors must be switched to fail safe position.	
6.6.19.6	Actors: Identification labels must be fixed undetectably (e. g. on the base plate of a valve but not on interchangeable valve) and must be resistant against materials used in the system and its environment.	
6.6.19.7	Actors must be protected in useful groups to enable easy and quick localization of possible error/failure (short circuit).	
6.6.19.8	**Wiring and installation**	
a)	Final wiring between the single components, machines and devices must be installed. It must be stable and equipped with step protection. Signal and data lines must be	

Specifications		Remarks
	separated from power lines.	
b)	In the technical area wires should be run in grating channels.	
c)	Metric packed screwing with segments should be used as cable ducts.	
d)	Corresponding to the ambient conditions as well as mechanical and chemical load caused by the system and its materials, suitable cable types must be installed. The cable types installed must be described in the machine documentation.	
6.6.19.9	**Switching and control systems**	
a)	The switching and control cabinets should not prejudice access to the PU so that maintenance and repair works can be carried out without problems.	
b)	Multiple terminals are not admissible, except double terminals.	
c)	Modem (with activation switch) to be installed for online problem redressals. Supplier to install an Ethernet socket in the control cabinet to connect remote maintenance system. Remote maintenance is established by means of laptops which are connected to the Ethernet socket by the maintenance technician.	
d)	On-line determination of Eutectic point measuring sensor for product temperature and resistivity to be provided.	
6.6.19.10	**Supply**	
a)	Adjustments must be corresponding to the requirements for selective switch- off	
b)	Feed-in to be supervised on low voltage and phase failure. Supervision to be registered in the pertaining automation system.	
c)	Feed-in must be assigned on input terminals in the control cabinet and conducted over a switch.	
d)	Control voltage supply must be provided: • SCADA/ Computer • PLC • Decentralized I/O system • As well as all other control and instrumenting components (actors/sensors) • All network components concur	
e)	Additional auxiliary voltage required (e. g. 24 V) must be generated in the system itself and distributed selectively.	
f)	Signals and control commands from the control system must be switched to decentralized I/O modules or I/O modules of the automation system respectively	
g)	Power control units, power outputs, electronic devices and circuits of the control system must be arranged and designated according to EMC (EMC guideline 204(108/EU for electromagnetic compatibility).	
6.6.19.11	**Field Bus**	
a)	Profibus DP to be installed as field bus system for connection of periphery.	
b)	Connection of Profibus DP components generally to be equipped with screened connecting plugs, termination resistors which can be switched off and additional programming socket.	
c)	Supplier to issue measuring protocols for all data lines (Profibus, network, LWL etc.) showing function and capacity.	
6.6.19.12	**Automation system (AS) control**	
a)	For safety relevant functions, the correspondingly fail safe hardware (e. g. Safety Integrated, F controls) must be applied. Field bus system users installed at site should be connected to the AS.	

Specifications	Remarks
b) I/O cards can be used for the AS. This must be specified.	
c) Continuation must not be possible without acknowledgement and new start by the operator.	
d) Connection to all systems involved to be established automatically, i. e. in case of failure of one component, connection must be established automatically after repair.	
6.6.19.13 **PC as Operating System**	
a) Industrial PC to be provided for freeze dryer data management with monitors of at least 19 inch size.	
b) An Ethernet network card and cable for connection to network must be provided.	
c) For data recovery (e. g. after hard disc failure), corresponding programs, back-ups and descriptions must be supplied. By means of these systems it must be possible to restore 5 GB data per hour. Data manipulation must be excluded.	
d) Easy machine operation by clear structures of the operating panel to enable the operator to view all relevant information.	
e) The main operating panel must be installed on the loading/unloading side.	
f) Layout of Templates: Industry standard templates to be provided to represent the utilities, process parameters etc.	
g) Provision for manual operation of all the sequences connected to the PLC to be made for controlling lyophiliser cycle manually.	
h) Operating system should be of the latest user adaptable version.	
6.6.19.14 **Software Development**	
a) Development of the software applied according to current version of the GAMP standard. Critical parameters, modification of user level and limit values are protected by password or equivalent authorizations	
b) Supplier of the automation system to deliver all application software to realize required functions, displays, protocols etc. as source code.	
c) Storage Capacity: A storage capacity must be specified at which data are deleted in order to avoid an overflow.	
d) Cycle Time: The cycle times can be freely selected and can be allocated to the single measuring points according to the process and system requirements.	
e) CPU capacity utilization: Capacity utilization of the PLC storage must not exceed 50% of the available capacity.	
f) All information including data display and software language should be in English.	
6.6.19.15 **Display and operating components**	
a) OS's to be connected to the automation system via available interfaces.	
b) OS to be installed in the system to the PC through SCADA.	
c) An audit trail must be integrated in the OS. The audit trail must include at least: • user ID • date (day, time) • parameters • old value • new value • It must be possible to read out the audit trail from the OS and store	
6.6.19.16 **Measurement and Sensors**	
a) Measurement and sensorics of the system to be connected to the pertaining	

Specifications	Remarks
decentralized I/O and control systems resp. with clear identification label.	
b) For internal device errors the measuring device must be adjusted to generate a defined malfunction being detected by the control system. eg. at a temperature range of 80 - 120 °C, 40 °C may be a malfunction.	
c) GMP relevant measurement must be suitably calibrated, mainly by means of 3 point calibration over the complete measuring chain. The corresponding calibration points should be within the required measuring range.	
d) Measuring devices must be easily detachable from the process, if required, shut-off units or relief facilities (e. g. for pressure) resp. must be provided.	
e) For all devices installed in the measuring chains, adjustment facilities must be specified or adjustment must be described, and complete operating instructions must be supplied.	
f) Measurement and sensors must be particularly easily accessible and interchangeable.	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Viral Vaccine Formulation Block** of **Integrated Vaccines Complex**, Chengalpattu.

i. **F1- LYO 01**

Equipment Location:

Block: **Viral Vaccine Formulation Block-Rabies**

Floor: **Ground floor**

Room No.:**F1G044**

Room Dimension : **230 sq.m (Technical area)**

Available room dimensions for equipment: **5300mm x 8900mm**

Slab Height: **6.0 m**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.**

Physical condition of the rooms:

Liquid Filling Rooms (Lyophilizer loading and unloading areas)

1) Room No.: F1G043
2) Clean room Classification: Grade "B"
3) Differential Pressure: 65 Pa Absolute
4) Temperature maintained:22°C ± 2°C
5) Relative Humidity: Not more than 55%

ii. **F1- LYO 02**

Equipment Location:

Block: **Viral Vaccine Formulation Block-Measles**

Floor: **Ground floor**

Room No.:**F1G044**

Room Dimension : **230 sq.m (Technical area)**

Available room dimensions for equipment: **5300mm x 8900mm**

Slab Height: **6.0 m**

The equipment location is indicated in the relevant block of the layout enclosed as **URS**

Specifications	Remarks
Annex-1. **Physical condition of the rooms:** **Liquid Filling Rooms (Lyophilizer loading and unloading areas)** 1) Room No.: F1G086 2) Clean room Classification: Grade "B" 3) Differential Pressure: 65 Pa Absolute 4) Temperature maintained:22°C ± 2°C 5) Relative Humidity: Not more than 55%	

7.2 Available utility

Electricity	- Single (220 V) & 3 phase (420 - 440 V)	
Compressed air	-10 CFM	
WFI at 80 deg C	-2.5 m^3/hr	
Purified water	-2.5 m^3/hr	
Cooling water @ 30 to 35 °C	-26 m^3/hr	
Pure steam @ 3 bar	-240 kg/hr	
Soft water for ring water pump	-10 LPM	

Note:

- Vendor to confirm on the above utilities provided for the equipment.
- Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per utility requirements.
- Vendor to provide the all utility consumptions in detail for the equipment during pre-bid.

8.0 ABBREVIATION

Abbreviation	Definition
ANSI	American National Standards Institute
CIP	Clean In-Place
EU	European Union
FAT	Factory Acceptance Test
HBL	HLL Biotech Limited
I/O	Input / Output
IRS	Installation Requirement Specifications
GA	General Assembly
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
ISO	International Standards Organization
MOC	Material of Construction
NPI	NNE Pharmaplan India

PLC	Programmable Logic Controller
PRV	Pressure reducing valve
P&ID	Piping and Instrumentation Diagram
SCADA	Supervisory Control And Data Acquisition
SIP	Sterilization In-Place
QA	Quality Assurance
OS	Operating System
USFDA	United States Food and Drug Administration
WFI	Water For Injection

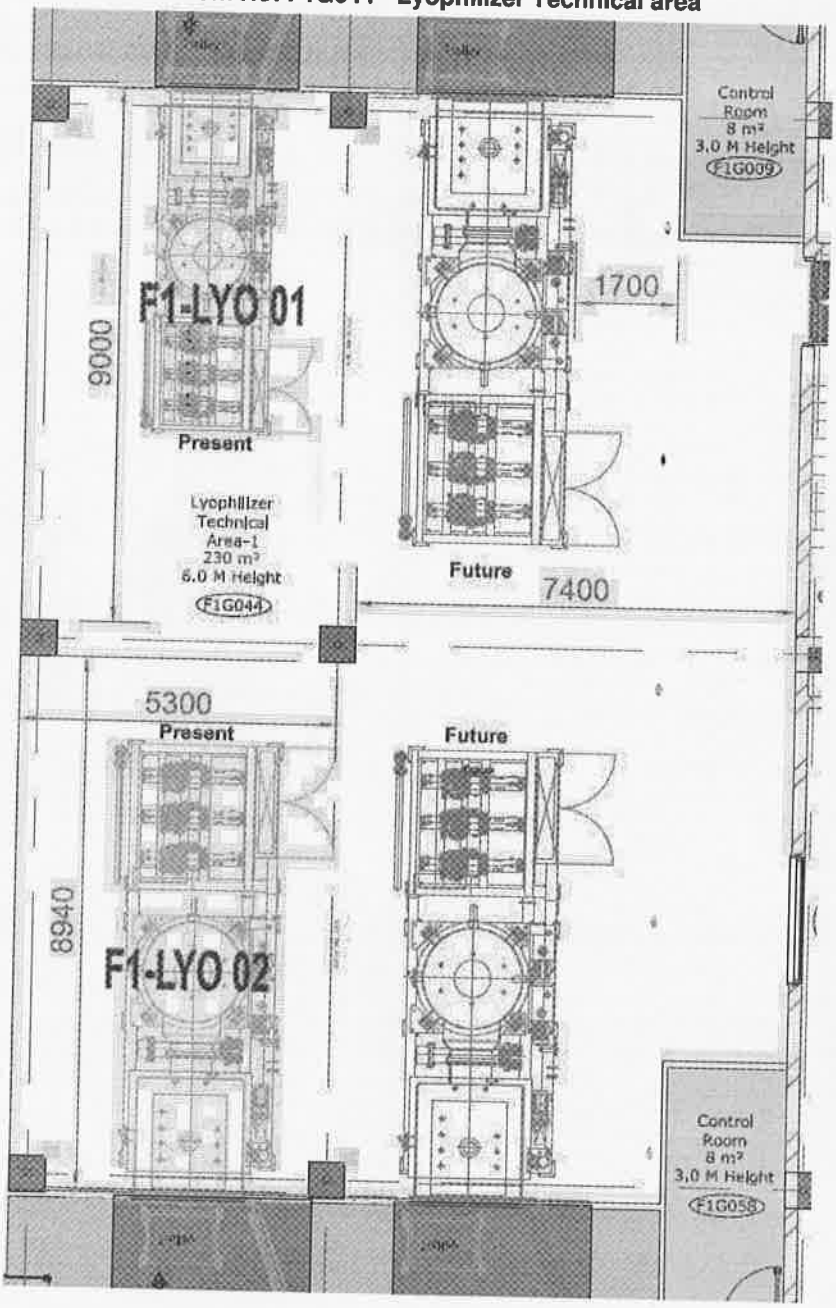
9.0 REVISION INDEX

Revision index

Revision	Date	Reason for revision
00	07-07-2014	First Draft for Client's Review
01	19-07-2014	Updated as per MoM dated 19-07-2014
02	01-09-2014	Point numbers 4.1.3, 6.6.6.1 & 6.6.16.6 are updated by HBL

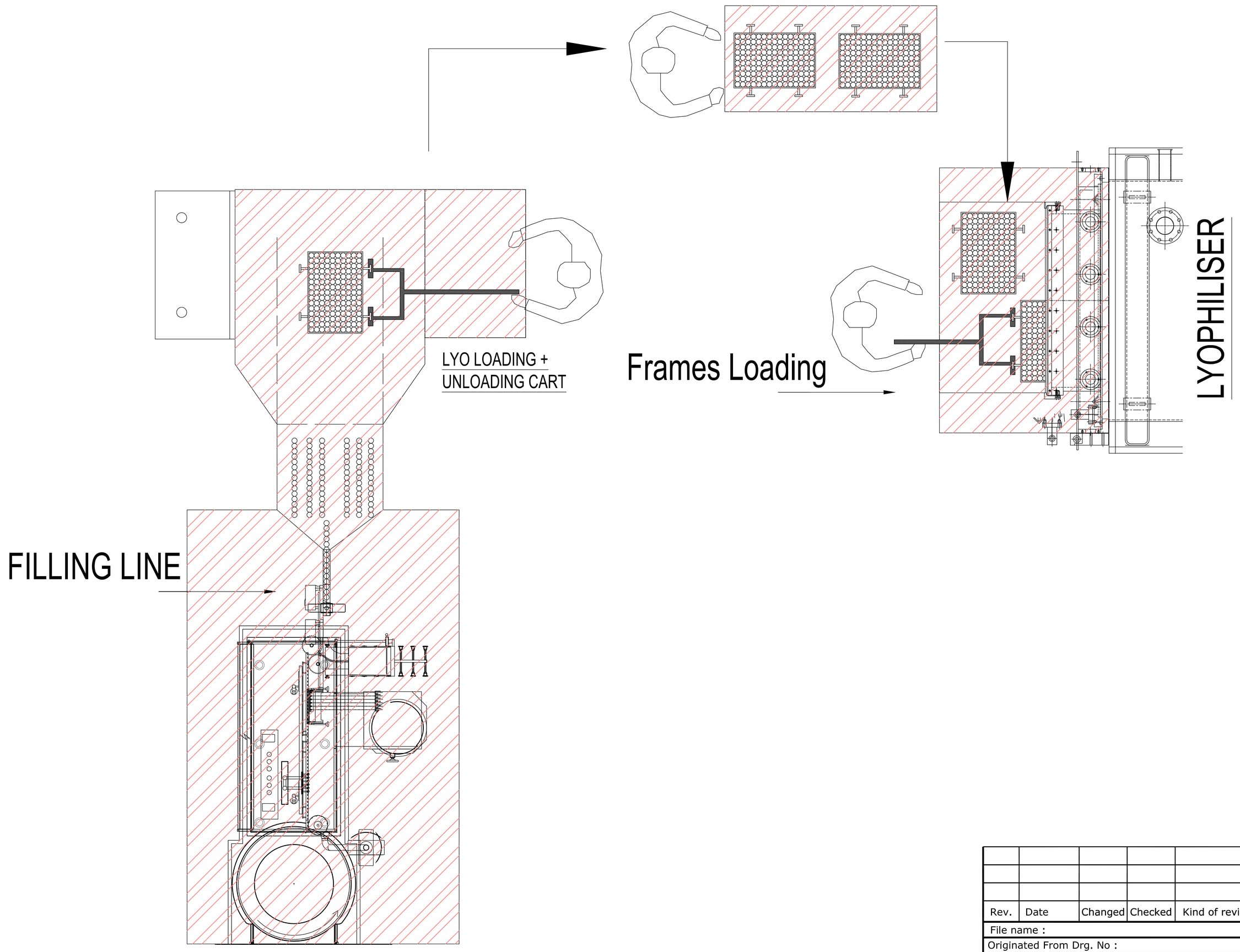
URS ANNEXURE 1: Layout showing location of the Lyophiliser technical area

Room No: F1G044 - Lyophilizer Technical area



URS Annexure - 2
List of components and make for Lyophilizer

S.No	Description	Preferred List
1.	Refrigeration Compressor Two Stage	Carlyle/ Bitzer/ Copeland
2.	Oil Separator	Henry/ Temprite/ Danfoss
3.	Suction Accumulator	AC and R / Henry GVN
4.	Refrigeration Valves	Danfoss / Sporlan / Henry
5.	Expansion Valves	Danfoss / Sporlan / Henry
6.	Plate Heat Exchanger	Alfalaval / Danfoss /WTT
7.	Refrigeration Ball valves	Danfoss / Sporlan / Henry
8.	Vacuum Pump	Pfeiffer Vacuum / Edwards /Leybol
9.	Vacuum Valves	Elomatic / Danfoss / Tyco
10.	Vacuum Sensors	MKS
11.	Isolation Valves	Elomatic / Danfoss /Tyco
12.	Fluid Pump	Grundfos / Elmo /3M Pumps
13.	Steam PRV Sanitary	Spirax / Steriflow
14.	Steam Valves only Diaphragm	Gemu / ITT/SED
15.	Safety Valves Sanitary	Spirax / Steriflow
16.	Steam Traps Sanitary	Spirax / Steriflow
17.	Check valves Sanitary	Spirax / Steriflow
18.	Pneumatic Controls	Festo / Janatics
19.	Water Ring Pump	Atalntic Fludics / Nash Elmo
20.	Spray Nozzles	Spraying Systems USA / BETE USA
21.	Fluid Fittings	Swagelok / Parker / Gemu
22.	Hydraulic Pump	Bosch / Parker / Rexroth
23.	Computer System	DELL / SONY /HP
24.	PLC and Controls	Allen Bradley / Siemens
25.	Pressure Sensors	Wika / Endress Hauser / Honeywell
26.	Temperature Sensors	Omega / Wika / Endress Hauser
27.	Servo Motors	SEW Germany / Allen Bradley /Siemens
28.	Electrical Controls	Schneider Electric / Allen Bradley / Siemens



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INTEGRATED VACCINES COMPLEX.

Project No.: 120310

Location: CHENGALPATTU

nne pharmaplan®
NNE Pharmaplan India Limited
#12, Achiah Shetty Layout,
Bangalore - 560 080., INDIA.

Description:

URS ANNEXURE - 3

PROCESS FLOW DIAGRAM FOR LYO LOADING +UNLOADING CART

	Date	Name
Drawn	01.09.2014	SAPL
Checked	01.09.2014	MJY
Approved	01.09.2014	VKKA
Scale- NTS	Units : mm	Size : A4

Drawing no: NPI/120310/PFD(SCH)/01

Rev. 00