



HLL BIOTECH LIMITED				
INTEGRATED VACCINES COMPLEX, Chengalpattu				
nne pharmaplan®	User Requirement Specifications			 <b>HLL BIOTECH LIMITED</b> <small>(Subsidiary of HLL Healthcare Limited)  (A Government of India Enterprise)</small>
	Equipment/System	Brine Chiller		
	Identification #	U-CHB 01/02/03	Document# URS/U/CHB 01	
	Effective Date	22.03.2014	Revision# 01	
	Tender No	HBL/IVC/HVAC/CHILLER/2014-15/02		
<div> <div>User Requirement Specifications</div> <div>Chilled Brine Generation System</div> <div>Equipment ID: UTY/BC/01T003</div> </div>				
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HLL BIOTECH LIMITED  
(Subsidiary of HLL Lifecare Limited)  
(A Government of India Enterprise)

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### Annexure List

Annex No.	Drawing / Document No.	Detail
1	NPI/120310/DS/U/CHB 01.	Data Sheet for Chilled Brine Generation System . 100TR ,

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### 1. APPROVAL SIGNATURES

This document is prepared by project team of NNE Pharmaplan for the %Integrated Vaccines Complex (IVC)+ (NPI project number: 120310) of HLL Biotech limited under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team/Engineering team of HLL Lifecare limited, and authorized by the appropriate Project Authority.

NNE Pharmaplan India Ltd.	Name and Designation	Signature	Date
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HLL Biotech Limited	Name and Designation	Signature	Date
<b>Reviewed By</b>	<b>Mr Sabarinath M</b> Asst. Manager (P-HVAC)		
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<b>Approved By</b>	<b>Mr Gnanaraj R</b> Manager (P-ME)		
<b>Authorised By</b>	<b>Mr Rajesh K. Gupta</b> Chief Operating Officer		

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2. 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 "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

For this purpose, NNE Pharmaplan has been appointed as consultants for setting up this facility, incorporating the latest standards of GMP and best practices.

2.2 Objective

This document is mainly prepared to define the requirements for the Chilled Brine generation system. The system is a package unit assembled and tested in the vendor's place.


The VENDOR being the organization which will respond to this tender by a quotation and subsequently is contracted accordingly.

It is the responsibility of the VENDOR to get familiar with the local situation prior to the start of the design work either by studying building and layout drawings or by an inspection on site.

The client expects from the vendor a careful review of the supplied documents with special regard to:

- Consideration of recent knowledge in science and technology
- Consideration of latest Indian regulation requirements
- General engineering rules as well as other regulations and guidelines to be considered
- Unlimited qualification/suitability/adequacy for the planned use/scope of work
- Warranty to provide a defect free, operative performance/service
- In case the text of an item in the specification allows different interpretation the vendor/bidder is obligated to indicate this in the proposal. Unclear passages have to be mutually clarified with the client prior to signing the contract. If the vendor fails to do this, the interpretation of the client applies.

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<h3>2.3 Responsibility of the Vendor</h3> <p>The scope shall be to design, manufacturing, Testing / inspection, transportation, loading, unloading, erection and Commissioning of air cooled chilled Brine generation system. The vendor should accordingly consider all necessary items required for effective installation and performance of the system, whether mentioned or not in the specifications.</p> <p>The vendor shall clearly indicate the battery limits, the termination points, utilities required, etc., in the detailed offer.</p> <p>The vendor shall come back with any suggestions if, found to be more effective and efficient / better than that specified in this specification.</p> <p>Client shall be entitled to inspect and audit the supplier's Quality Management System (QMS) and the facilities, if desired, prior to any business agreement.</p> <p>The vendor should take full responsibility for the function of the chilled Brine generation system.</p> <h3>3. CODES &amp; STANDARDS</h3> <table border="0"> <tr> <td>ARI 550/590. 2003</td> <td>Performance rating of water chilling packages using the vapor compression cycle</td> </tr> <tr> <td>ARI 575:</td> <td>Air Conditioning and Refrigeration Institute. Standard Method of Measuring Machinery Sound within Equipment Rooms (Base of all data presented or field testing of equipment with relation to sound requirements).</td> </tr> <tr> <td>ASME Section VIII:</td> <td>American Society of Mechanical Engineers Code for Unfired Pressure Vessels (Design, construction, testing and certification of pressure vessels).</td> </tr> <tr> <td>ANSI-B 9:</td> <td>American National Standards Institute. Safety Code for Mechanical Refrigeration (overall general safety requirements, relief device sizing, etc.)</td> </tr> <tr> <td>ANSI-B 31.5:</td> <td>American National Standards Institute -Code for Refrigerant Piping.</td> </tr> <tr> <td>ASHRAE 15:</td> <td>Safety code for Mechanical refrigeration</td> </tr> <tr> <td>ASHRAE 23:</td> <td>Methods of testing and rating positive displacement refrigerant compressors and Condensing units</td> </tr> <tr> <td>ASHRAE 30:</td> <td>Methods of testing liquid chilling packages</td> </tr> </table>					ARI 550/590. 2003	Performance rating of water chilling packages using the vapor compression cycle	ARI 575:	Air Conditioning and Refrigeration Institute. Standard Method of Measuring Machinery Sound within Equipment Rooms (Base of all data presented or field testing of equipment with relation to sound requirements).	ASME Section VIII:	American Society of Mechanical Engineers Code for Unfired Pressure Vessels (Design, construction, testing and certification of pressure vessels).	ANSI-B 9:	American National Standards Institute. Safety Code for Mechanical Refrigeration (overall general safety requirements, relief device sizing, etc.)	ANSI-B 31.5:	American National Standards Institute -Code for Refrigerant Piping.	ASHRAE 15:	Safety code for Mechanical refrigeration	ASHRAE 23:	Methods of testing and rating positive displacement refrigerant compressors and Condensing units	ASHRAE 30:	Methods of testing liquid chilling packages
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#### 4. SCOPE OF SUPPLY

This requirement and respective document attached shall define the minimum requirement to be met by the vendor.

The scope shall include but not limited to design, supply, Testing / inspection, transportation, erection, Commissioning of Water cooled, screw type Brine Chiller of capacity as mentioned in the table below with chilled brine outlet temperature shall be (-)4°C and inlet to chiller to 1°C. Cost required for FAT shall be quoted separately.

Equipment	Capacity	Quantity
Water Cooled Brine Chiller	100 TR	3

The Vendor shall supply the chiller package that is necessary to meet process requirement. The package shall have a common steel base structure with all system components, related valves and including the following equipment, but not limited to:

- Compressor with lubricant system
- Water cooled Condenser
- Expansion Valve
- Evaporator
- All piping, fittings (including mounted appurtenances) within chiller & auxiliaries.
- groove coupling with Bolts, Nuts and Gaskets for inlet & outlet for condenser and evaporator side as per standards
- Steel Base structure
- Instrumentation
- Control panel along with control Cable between chiller power & control panel and its relevant equipment, automatic valves, instruments and local control cabinet.

#### Control panel shall have the following features:

- a. Microprocessor based controller with provision to export the data for BMS, provision of Ethernet Connectivity to BMS (Bidder to specify details).  
Microprocessor with HMI panel shall provide access to real time & historical trends and events

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relating to the respective control loop, alarm screens and alarm acknowledgement. The instruments, gauges, transducers etc. required to display the parameters listed below are in the scope of successful vendor.

- Chiller Run Status
- Chiller On / Off command
- Compressor Runs Status
- Compressor Gas Pressure
- Current
- Expansion Valve Position
- Date and time
- Chiller operating hours
- Entering (inlet) chilled brine temperature
- Leaving (outlet) chilled brine temperature
- Entering (inlet) condenser side temperature
- Leaving (outlet) condenser side temperature
- Evaporator refrigerant temperature
- Oil pressure
- Oil-sump pressure
- Evaporator pressure
- Condenser pressure
- Number of starts
- Leaving evaporator temperature
- Motor Amperes
- Motor Amperes at set point
- Remote reset signal
- Critical sensor value at the time of fault
- Any other

b. Power and control circuit terminal blocks

c. ON/OFF control switch

d. Vendor to specify the Controls & other Features involved in the system


Data display: Bidder to specify all the data available to display.

- Power Cable between chiller power & control panel and its local control cabinet.
- Refrigerant and lubricant for first filling
- Chiller shall be equipped with 2 oil filters for changing filter online.
- Motor



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### 5. DESCRIPTION OF PACKAGE SYSTEM

#### ❖ Design Basis:

- Type: Screw type water cooled Brine Chiller with constant speed.
- Operating Temperature: (-)5°C to 0°C
- Cooling Media: Cooling Water
- Refrigerant: R 134a or similar ozone friendly refrigerant
- Noise level: 80dB (A) 1 meter from equipment
- Brine Used: MEG (Mono Ethylene Glycol)
- Brine Concentration: 20% to 40% by mass (Vendor to confirm with respect to the mentioned required temp.)

Chiller shall be designed for following duty conditions

- Summer DBT: 39.4°C
- Monsoon DBT: 28.3°C
- Winter DBT: 18.3°C
- Max R H: 88%
- Min. R H: 41%
- Altitude (above MSL): 30 Feet


#### ❖ Compressors

The compressors shall be quiet twin rotary semi hermetic screw type with low vibration levels, equipped with:

- A two-pole electric motor cooled by suction gas and protected by internal temperature sensors.
- An oil charge of synthetic polyester oil with a level check sight glass and an electric crankcase heater.
- An electronic protection board to ensure compressor control, over temperature protection, verification of the crankcase heater operation and high-pressure safety switch control.
- Low noise and low vibration levels shall be guaranteed by supplier.
- Compressor mountings that are independent from the unit chassis and installed on flexible anti-vibration blocks.

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- Suction and discharge piping support on the compressor discharge side, directly attached to the compressor base to prevent the transmission of vibrations to the unit chassis.
- An acoustic compressor enclosure reducing radiated noise.
- Inbuilt oil separation system.

### ❖ Evaporator

The unit shall be equipped with a direct-expansion shell-and-tube / Flooded type evaporator with single/two refrigerant circuits.

- The maximum refrigerant-side operating pressure shall be 235 psig and the maximum pressure on the heat exchange fluid side shall be 150psig. The evaporator shall be tested with pressurized dry air; no oil test shall be required.
- The weld-free copper tubes shall be internally finned and expanded into the tube sheets. The brine water inside the shell shall be routed by polypropylene baffles solidly fixed to the tubes.
- The evaporator shall be mounted on support feet with thermal bridge rupture and shall be integrally insulated polyurethane foam.
- The evaporator shall be equipped with a drain and a purge plug.

Unless specified otherwise, the fouling factor for chiller shall be 0.0001 sqft hr ° F/ BTU

### ❖ Condenser

#### 1) Condenser


Condenser shall be of the shell-and-tube type, even pass, designed for adequate working pressure. Shell will be fabricated from rolled carbon steel plate with fusion welded seams. Copper tube sheets shall be drilled and reamed to accommodate the tubes. Tubes shall be of high-efficiency, internally and externally enhanced type having plain copper lands at all intermediate tube supports to provide maximum tube wall thickness at the support area. Each tube will be roller expanded into the tube sheets providing a leak-proof seal and shall be individually replaceable.

The condenser shall be water cooled design. It shall be complete with the following connections and accessories:

- Water inlet and outlet (with grooved coupling).
- Drain and vent connections with stop valves.
- Electronic type Gauges pressure and temperature Gauges shall be provided.

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- De-scaling valves
- Water flow switches at the outlet

Unless specified otherwise, the fouling factor for condenser shall be 0.001 sqft hr ° F/ BTU. It shall be complete with the accessories.

### ❖ Electric Motor

Motor shall be energy efficient and suitable for 415 volts, 3 phase, 4 wire, 50 Hz supply. Hermetic/semi hermetic motors shall be suction gas cooled, two pole, squirrel cage induction types. In case of open compressor type motors shall be screen protected drip proof squirrel cage induction type. Motor shall be designed and guaranteed for continuous operation. Insulation of motors shall be Bqclass. Temperature rise of motor under rated service conditions shall not exceed 80 °C (by resistance method of measurement) over an ambient of 40 ° C. the motor shall be provided with a combination of ball and roller bearing.

Starting current at rated voltage and frequency shall not exceed 2 times of full load current at rated voltage and frequency.

Terminal box of sturdy construction shall provide enough space for terminating, connecting and earthing of copper conductor cable. All terminal boxes shall be located at the same side of the motor and have terminal and cable glands suitable for the specified cables.

Starting current at rated voltage and frequency shall not exceed 2 times the full load current at the rated voltage and frequency. The total efficiency shall include losses of the auxiliaries such as independent excitation, motor-driven fans, lube-oil pumps etc. Over voltage surge protection shall be provided to protect motor.

### ❖ Refrigerant Circuit


Each refrigerant circuit shall include: a discharge valve, a leaving fluid valve, an electronic expansion device, equipped with a liquid sight glass to show the opening, a filter drier with replaceable cartridge, liquid receiver and separator, pressure and temperature sensors that can be removed without draining the refrigerant charge, one high- pressure switch with automatic reset per compressor complete with HFC refrigerant charge. All refrigerant circuit components shall be welded for total and lasting leak-tightness.

### ❖ Power Control Boxes

- The unit shall operate at 400 - 415 Volts, 3 phases, 50 Hz without neutral and shall only have one power connection point.
- The control circuit voltage shall be 24 V maximum, supplied by a factory-installed transformer.

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- The unit shall be equipped with a factory-installed interlockable disconnect/isolating switch.
- The power and control circuit wiring shall be arranged so that isolation of one circuit of chiller shall be possible for both power and controls.

### ❖ Chassis/Enclosure

Chassis and enclosure made of galvanized sheet steel. Painted in oven-baked polyester powder paint in light grey colour. The removable panels and the doors shall be accessible.

### ❖ Unit Control

The chiller shall be equipped with microprocessor control panel regulating all unit operating and safety parameters in order to optimize energy efficiency and minimize the possibility of the refrigerant circuit shutting down due to a fault. The control system shall ensure the following functions:

- Entering and leaving brine temperature control by PID loop with equalization of the compressor operating times and number of compressor start-ups.
- Protection against excessive compressor cycling by auto adaptive control algorithm acting on the leaving brine set point dead band.
- Optimization of the condensing pressure with a floating set point based on the outside temperature and the thermal load in order to limit power consumption.
- Dynamic evaporator superheat control via the electronic / suitable expansion valve (EXV) in order to maximize the use of the evaporator capacity, whilst protecting the compressors against migration of liquid refrigerant.
- Periodic fan start-up when the unit is shut down in order to prolong the operating life of the fans.
- Automatic compressor unloading when an abnormally high condensing pressure is detected to prevent the shutdown of the refrigerant circuit due to a high-pressure fault.


### ❖ Machine-Operator Interface

- This shall include status and fault LEDs, two numeric indicators, a synoptic refrigeration system display and a command keyboard.
- The interface shall permit display of brine water and outside air entering/leaving temperatures, compressor suction/discharge pressures and temperatures, set point, compressor operating times and the number of compressor start-ups.
- Chiller diagnostics and parameter setting by selecting one of the following menus:
- Information, temperatures, pressures, set points, inputs, test, configuration, alarms, alarm history,

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operating time.

### ❖ Automatic Operation

- The chiller shall be equipped with a programming timer, permitting
  - Unit on/off setting
  - Changeover to the second set point (unoccupied mode)
  - Demand limitation
- The controls and safety devices shall ensure the following
  - On/off mode based on the outside temperature
  - Set point reset based on the outside air temperature or the return brine water temperature
  - Manual reset high pressure switch
  - Automatic reset high pressure switch managed safety device with limited thresholds
  - Automatic reset low pressure switch managed safety device with limited thresholds
  - High pressure safety valve
  - Anti-freeze probe on evaporator outlet
  - Chilled brine temperature probe located on the evaporator inlet
  - Compressor and fan thermal cut-out devices
  - Mechanical flow switch fitted as standard.

## 6. GENERAL REQUIREMENTS

### 6.1 Safety Requirements:

Vendor shall consider all safety requirements in accordance with good engineering practices and local regulation.


The VENDOR is fully responsible for the accordance with all appropriate regulations.

The noise level of the system shall be as low as possible, and must not exceed 70 dB(A) measured at operator working places.

In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the article remain in a safe condition.

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### 6.2 Name Plates:

Each item shall carry a nameplate in accordance with client's standard which shall be fitted in a conspicuous position on brackets projecting 25 mm or Equivalent from the vessel or insulation as applicable. Equipment tag number shall also be included.

### 6.3 Painting:

Outside carbon steel surfaces (other than machined) shall be thoroughly cleaned, scale free and shall be painted with two coats of approved enamel paint. Outside stainless steel surfaces shall not be painted.

## 7. MATERIAL SPECIFICATIONS

### 7.1 General

All valves and filters arranged for easy operation, service and handling. Utilities are provided according to installation drawing.

### 7.2 Appropriate Materials

Appropriate materials of manufacture must be selected and specified on the specific application and process requirements and certificates must be supplied as requested by the customer/purchaser or as usually necessary.

Material of labelling on equipment and instruments shall be of durable type. They shall be resistant against cleaning detergents (e.g. 70% ethanol). Installation of tags has to withstand temperature influence and mechanical demands typical for normal transport, installation and operation, so that they are captive to the equipment.

### 7.3 Piping

- The pipe class specified for chilled brine piping is ERW carbon steel pipes and fittings:
- Pipe according to ASTM A135, ERW, Schedule -10 for sizes above 40 NB and ASTM A135, ERW, Schedule -40 for sizes below 40 NB
- Apart from the pipes, the piping system consists of:
- Ball valves / Butterfly valves (manual operated)
- Check valves, strainers etc
- Pressure gauges and temperature gauges

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- Pipes, elbows, T-pieces, reducers
- Detachable connections Pipe supports, hexagon bolts and nuts.

### 7.4 Non-metallic materials

Cables inside the production unit shall be resistant against heat, pressure and steam.

### 7.5 Insulation materials

Any material used for insulation must be free of asbestos. Insulation material shall be of low chloride content and shall comply with current standards for thermal insulation. Thickness of insulation is to be specified by the vendor.

Vendor shall mention the thickness & insulating material details in the offer. Vendor shall carry out the insulation works including the material supply & installation. The special insulation works to be applied on Chiller skids shall also be provided by Vendor. Vendor shall provide all the details of insulation works. The insulation of Chiller units shall be selected based on thermal design and the performance guarantee of the package.

The appropriate space for insulation application shall be duly considered by Vendor during package detail engineering phase.

## 8. CONSTRAINTS

### 8.1 Equipment Location

Block name	Location
Utility Block	Indoor

### 8.2 Available Utilities


The following media interfaces are provided:

- Electrical power 415 V/ 3 Phase/4 Wire/ 50 Hz
- Compressed air
- Soft water
- Cooling water 32°C

Connecting points of all utilities, consumption and capacities of the required utilities shall be advised with the quotation.

# HLL BIOTECH LIMITED

## INTEGRATED VACCINES COMPLEX, Chengalpattu

nne pharmaplan®	User Requirement Specifications				 HLL BIOTECH LIMITED (Subsidiary of HLL, Ucare Limited) (A Government of India Enterprise)
	Equipment/System	Brine Chiller			
	Identification #	U-CHB 01/02/03	Document#	URS/U/CHB 01	
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### 9. DELIVERY AND INSTALLATION

Vendor shall be responsible for the delivery of the complete Package Unit to **HLL Biotech Limited, Integrated Vaccines Complex, Chengalpattu.**

Vendor shall be responsible for the positioning and installation of the complete Package Unit, including tie in of utilities and media supply.

The responsibility for packing, transport and insurance is with the Vendor of the system. The costs must be included in the offer as separate price.

Before packing and dispatch, the system must be well cleaned inside as well as outside and dried. For the transport, the system shall be completely empty and dry. The packing shall be rigid to protect the PU against damage.

All nozzle flange faces shall be coated with easily removable rust preventative grease and shall be further protected with a wood or metal cover to prevent damage during shipment. Threaded connections are to be protected with thread protectors. Machined surfaces are to be covered with temporary metal protective. Both partly fabricated and completed items liable to suffer distortion during transit and erection shall be braced. Open ends shall be covered to keep out dirt and other foreign matter. Spare gaskets, bolts, nuts, etc., and any other loose items shall be boxed separately from the main equipment. Such boxes shall be suitable for site storage and clearly and permanently marked to show:

- Order number
- Item number (for which the parts are intended)

The item number shall be prominently painted on the side of the equipment.

All loose items have to be carefully fixed or packed in a separate box.

The Package Unit shall be equipped with appropriate lifting lugs and provisions for transport allowing easy loading, offloading and transportation inside the building.

#### 9.1 Installation

The erection and installation of the system is part of the scope of supply.


The system must be transported to the erection place and placed in position under the supervision of the Vendor representative.

The compressors, coolers and condensers shall be mounted on a common foundation. The vendor shall make his own arrangement for supplying all the materials and labour required for the foundations and shall supply and install all accessories such as foundation bolts, nuts, washers, leveling scrolls, mounting frame or base plate, spring vibration isolation devices, etc. as required.



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The compressor and motor assembly shall be mounted on a spring isolated base. Every compressor motor set shall have its own mounting base. Condenser and cooler associated with the compressor shall also be mounted on the same base with supporting frame work. The compressor shall be held down by means of bolts and nuts and the motor shall be mounted and held down on to the slide rails provided on the base.

Vibration isolation of the base from the floor shall be effected by anti-vibration cushy foot mountings with neoprene rubber. Cushy foot mountings shall be complete with leveling scrolls and lock-nuts to be provided.

The vendor shall supply the required first charges of refrigerant, lubricant, and other necessary consumables factory installation, testing and commissioning of the equipment and shall observe due care with regard to leveling of the equipment before grouting the foundation bolts.

### 9.2 Spare Parts

The spare parts for commissioning and start-up are included in Vendor scope of supply. List of commissioning and start-up spare parts has to be included in the bid based on the selected Manufacturer's models.

Spare parts required for two & five years of trouble free operation shall be listed and quoted separately item by item.

## 10. TESTING & COMMISSIONING:

Testing and commissioning will be carried out by the VENDOR. The customer/purchaser and / or his / her representatives have the right to participate in testing and commissioning.

The vendor shall upon the commissioning the equipment conduct capacity computation tests to establish the design capacity of the equipment. The refrigeration capacity shall be computed from the test readings of chilled brine temperature readings, brine water flow measurements (measured by means of flow meters) and the energy consumption shall be recorded by suitable energy meters. The computed results should tally with the specified recorded by suitable energy meters.

Inspection and tests shall be made by Vendor in accordance with requirement requisition document and/or any correlative standards and codes.


During testing and commissioning future operators/technicians shall be trained in all equipment / system functions (e.g. preparation, start-up, operation, shut down, maintenance, etc. - as far as applicable).

All testing and commissioning documents, recordings and reports shall be in English language.

The VENDOR shall notify the customer/purchaser one month in advance of the start of FAT.

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### ➤ QAP:

Vendor to submit a detailed quality assurance policy along with offer for hold, review, witness points at factory and at site.

### ➤ Testing:

If in case Vendor proposes a testing procedure the same shall be approved by Client.

### ➤ Inspection:

Client reserves the right to carry out inspection & further performance at any time during fabrication before shipment. Inspection shall be done by the Client or their representative and / or their nominated inspection authority.

### ➤ Factory Acceptance Test (FAT):

Pre-requisite for shipping is client / client's representative witnessed and approved FAT and FAT record (If required).

The FAT shall consist of the following checks:

- Check conformance to the Specifications provided and the specifications of Vendor.
- Check for completeness of equipment group.
- Check for dimensions.
- Check for materials.
- Verify the correctness of Name plate data.
- If possible - simulation of some complete operation cycles, Verification that all alarms and interlocks work as specified.
- Review of the complete specified documentation package.
- Review of equipment conformance with relevant codes and guidelines.
- Equipment performance test. This shall include the routine test & the performance. The performance test shall include the power consumption, noise level, PLC simulation test, etc., under varying capacity conditions.


A prior notification shall be issued to client for witnessing the FAT (If required).

The performance test shall include the detailed performance test condition like test standard, test instrument, preparation & procedures, test method, test record template.

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(Subsidiary of HLL Healthcare Limited)

(A Government of India Enterprise)

All Vendor's internal testing before handing of the FAT should be documented properly according to Vendor's internal procedures. Tests reports should be available before client / client representative's arrival at Vendor shop for FAT (If required).

The tests shall be carried out at vendor's expense. Utilities for operating the equipment shall be provided by Vendor.

If the test record does not meet and perform in accordance with Vendor warranty obligations Vendor will, at its expense, implement all the necessary modifications and afterwards the tests will be repeated.

After the approval from the client / client representative's approval, the system will be prepared and shipped to the site.

The acceptance of any piece of equipment or component by client or their representative does not relieve the Vendor of any responsibility for complying with the provisions of this specification or of any guarantee.

### ➤ Site Acceptance Test (SAT):

The final acceptance tests at site will be carried out after system delivery on site and mechanical completion of the system. The purpose of the SAT is to verify that the system is supplied, installed and that it operates according to the relevant specifications. The SAT testing includes:

- Check of completion of open items from FAT
- Check of transport damages
- Check scope of supply
- Proper operation of the systems
- Site performance test
- Verification of final documentation.


As far as site performance test is concerned, the supply includes: detailed test procedure, check lists and Vendor's specialist assistance during the test according to a schedule to be agreed upon.

Vendor has to submit a proposal including site supervision and assistance during commissioning and start-up of the package unit. The procedure and schedule of the performance test and relevant acceptance criteria shall be defined / agreed upon between vendor and the client.

Vendor shall record all the results of the tests carried out and submit the report to the client for approval.

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### 11. DOCUMENTATION

#### 11.1 General

Brine chiller package is not a qualified package. However, vendor shall follow Good Engineering Practices.

All documentation for the Brine Chiller system shall be distinctly marked with Unique Name, Identity No. and revision No.

As English is the project language, the documentation must be in English.

Specified list of all delivered documents, such as test protocols, drawings and specifications.

The documentation shall be delivered as four paper copies and one electronic version (CD-ROM). The documentation shall have final % as built+status.

The documentation provided by the vendor must allow


- Training of operators
- Operation, maintenance and calibration (Complete technical documentation)
- Testing or Qualification of equipment incl. generation of related documents (Testing plan, IQ, OQ, PQ).


#### 11.2 Documentation Packaging for Offer

- Dimensions for space needed for installation.
- Unit size dimensions.
- Utility consumptions
- Weights
- GA Drawing in CAD

Vendor should provide a document list of their standard documentation together with examples for review and final approval by client. The review & approval of design documents will be as per good engineering practices. Client will check installation of system against design documents issued for construction according to good engineering practices.

Vendor shall submit before order placement the detailed supplier document index (to be approved by client), listing all drawings and documents that will be supplied and their delivery dates.

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<p>It is included in the vendor scope of work the preparation and supply of all documents (i.e. drawings, calculations, etc.) and all obligations requested by local Authorities, in order to fulfill the applicable laws &amp; regulations. Vendor shall provide the following list of documents for the complete package:</p> <p><b>11.3 List of Documentation</b></p> <p>VENDOR shall provide the following documents for the complete package unit:</p> <table border="1"> <thead> <tr> <th>Document Name</th> <th>Remark</th> </tr> </thead> <tbody> <tr> <td colspan="2"><b>General</b></td> </tr> <tr> <td>➤ Functional design specification</td> <td></td> </tr> <tr> <td>➤ <b>List of the used material:</b> List of spares &amp; consumables for trouble free operation for two and five years separately from the date of commissioning.</td> <td></td> </tr> <tr> <td>➤ Process description, functional description</td> <td></td> </tr> <tr> <td>➤ <b>Guarantee/ Warrantee:</b> 18 Months from the date of supply or 12 months from the date of commissioning whichever is earlier.</td> <td></td> </tr> <tr> <td colspan="2"><b>Schemes for approval</b></td> </tr> <tr> <td>➤ Quality Assurance Policy</td> <td></td> </tr> <tr> <td>➤ Data Sheets</td> <td></td> </tr> <tr> <td>➤ P&amp;ID drawings</td> <td></td> </tr> <tr> <td>➤ Layouts, overview plan</td> <td></td> </tr> <tr> <td>➤ GA Drawings</td> <td></td> </tr> <tr> <td>➤ Electrical &amp; Control circuit diagram and panel layout with dimensions.</td> <td></td> </tr> <tr> <td colspan="2"><b>Instrumentation</b></td> </tr> <tr> <td>➤ Input/output signal list</td> <td></td> </tr> <tr> <td>➤ Parameter list of intelligent instruments, valves</td> <td></td> </tr> <tr> <td>➤ Specification of hardware components and specification of battery limits</td> <td></td> </tr> </tbody> </table>						Document Name	Remark	<b>General</b>		➤ Functional design specification		➤ <b>List of the used material:</b> List of spares & consumables for trouble free operation for two and five years separately from the date of commissioning.		➤ Process description, functional description		➤ <b>Guarantee/ Warrantee:</b> 18 Months from the date of supply or 12 months from the date of commissioning whichever is earlier.		<b>Schemes for approval</b>		➤ Quality Assurance Policy		➤ Data Sheets		➤ P&ID drawings		➤ Layouts, overview plan		➤ GA Drawings		➤ Electrical & Control circuit diagram and panel layout with dimensions.		<b>Instrumentation</b>		➤ Input/output signal list		➤ Parameter list of intelligent instruments, valves		➤ Specification of hardware components and specification of battery limits	
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Document Name					Remark
➤	List of components				
➤	List of instruments				
Operation / Service / Electronic Data Service					
➤	Operation and maintenance manuals (including parts from sub- vendors)				
➤	Lists of spare parts with ordering information				
➤	Detailed manuals for single equipment				
➤	Technical datasheets for single equipments (including capacities)				
➤	Documentation of first calibration (certificate)				
➤	Calibration procedure ( calibration plan)				
➤	List of alarms including Trouble shooting				
➤	Scheme of program work flow.				
➤	Documentation of displays, tools for configuration				
➤	Source Code on disk. Software Installation CD.				
➤	Certificate of warranty				
➤	Maintenance contact				
➤	Plan of software structure (Overview of modular functions)				
➤	Version of installed software user levels				
➤	Certificate of data security				
Safety					
➤	Safety Procedures				If necessary
Training					
➤	Documented trainings for operators				
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### 12. QUALITY ASSURANCE

The VENDOR must have a well-implemented QM-system, e.g. ISO 9000 certification. Capability and experience in working for the GMP-related industry must be proven. Auditing of QM-system with focus on software development methods / strategy has to be possible.

A quality assurance plan has to be delivered latest with placement of order.

### 13. ATTACHMENTS:

1. Data Sheet for Brine Chiller. Document No.: NPI\_120310\_DS\_U\_CHB 01/02.

### 14. REVISION INDEX

Revision	Date	Reason for revision
00	2014.03.22	First Draft
01	2014.05.08	Document updated as per comments received on 02.05.14