HLL LIFECARE LIMITED (A Government of India Enterprise) CENTRAL ENGINEERING DIVISION P.B.NO.2, PEROORKADA.P.O, THIRUVANANTHAPURAM - 695 005 KERALA, INDIA

TECHNICAL& PRICE BID

SUPPLY, INSTALLATION, TESTING AND COMMISSIONING OF AUTOMATIC TWO LINE VERTICAL FORM FILL SEAL SACHET PACKING MACHINES FOR PERSONAL LUBRICANT

AT

HLL LIFECARE LIMITED PEROORKADA FACTORY, THIRUVANANTHAPURAM

IFB No : HLL/CED/LUBE/SITC/2LINE SACHET PACKING/MACHINE/2017

Date : 02.06.2017

HLL LIFECARE LIMITED (A Government of India Enterprise) CENTRAL ENGINEERING DIVISION

P.B.NO.2, PEROORKADA.P.O,

THIRUVANANTHAPURAM - 695 005 KERALA, INDIA Phn: - (++ 91 471) 2437270 Fax: - (++ 91 471) 2432647

INVITATION FOR BIDS (IFB)

IFB No : HLL/CED/LUBE/SITC/2LINE SACHET PACKING/MACHINE/2017

Date : 02.06.2017

HLL Lifecare Limited invites sealed and super scribed Technical and Price bids from competent and experienced eligible Suppliers for the following work at our Central Engineering Division.

SI.No.	Brief description of work	Quantity in Nos.	EMD (Rs.)
1	Supply, Installation, Testing and Commissioning of Automatic Two Line Vertical Form Fill Seal Sachet Packing Machine for personal lubricant at HLL Life care Limited Peroorkada Factory, Thiruvananthapuram	1.00	5,000/-

- 2. Eligibility criteria for issue of Bid document.
- a) Minimum 5 years experience in the relevant field
- b) The Bidder should have executed successfully completed SITC of similar type packing machines, each work costing not less than Rs.5Lacs during the last 5 years.
- c) Average annual financial turn over of the bidder during the last 3 years, ending 31st march of the previous financial year, should be at least Rs.50Lakhs.
- 3. A complete set of bid documents can be had from the Office of the Deputy General Manager (CED), Central Engineering Division, HLL Lifecare Limited, Peroorkada Factory, Thiruvananthapuram 695 005, Kerala, India during office hours on any working day on submission of written application along with the tender cost of Rs 550/- (inclusive of all taxes).

The Tender Documents can also be downloaded from our Website **www.lifecarehll.com** from the date of issue of tender document. Tender forms shall be filled in ink or typed. No tender filled in pencil shall be considered. The tenderer shall sign and seal the form at each page and at the end, in token of acceptance of all the terms and conditions of the tender.

Note:- In case the bidder downloads the tender form from our website, the bidder shall enclose DD for Rs 550/- (inclusive of taxes) as cost of tender along with the bid document.

- 4. The bid documents will be available up to 15.00 Hrs. on the previous working day of the opening of the bids.
- 5. The scheduled date for issue, receipt and opening of bids is as follows.
 - a) Date of issue of tender document 02.06.2017 onwards.
 - b) Last date and time for receipt of bids 21.06.2017 up to 15.00 Hrs.
 - c) Date and time of opening of bids 21.06.2017, 15.30 Hrs.
 - d) Address for communication, receipt and place of opening of bids:

Deputy General Manager (CED) Central Engineering Division, HLL Lifecare Limited (A Government of India Enterprise), PB No 2, Peroorkada, Thiruvananthapuram – 695005, Kerala State, India Ph: (++91 471) 2433374,2437270 –501,502 Tele Fax: (++ 91 471) 2432647 E-mail: rajeevrv@lifecarehll.com,

- 6. The completed and sealed bid documents and all schedules should be submitted to Deputy General Manager in the above address along with the EMD. Bids received after due date and time will be rejected. Any bid not accompanied by EMD will be rejected
- 7. Bidder should submit technical and price bid in separate envelop. Price bid will be opened only from the technically qualified bidders.
- 8. Bids will be opened in the presence of Bidders representative(s) who choose to attend on the specified date and time, at the office of HLL at the address given in Clause '5 (d)' above.
- 9. In the event of the date specified for bid receipt and opening being declared as a closed holiday for Owner's office, the due date for submission of bids and opening of bids will be the following working day at the appointed times.
- 10. The Owner may, at its discretion, extend this deadline for submission of bids by amending the Bid Documents or any other reasons, in which case all rights and obligations of the Owner and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.
- 11. Owner will not be held responsible for the postal delay, if any, in the delivery of the bidding document or the non-receipt of the same. Bids sent by Telex/Fax/Telegraph will not be accepted.
- 12. The company reserves the right to club or split the items of works, change the qualifying criteria at their discretion and to reject or cancel the Invitation for bids without assigning any reason thereof.

DEPUTY GENERAL MANAGER (CED)

SCHEDULE I

CONDITIONS OF BID

1. Definitions

- a. "Invitation For Bid (IFB)" shall mean and include the present document, and such other complements and agenda, which may subsequently be issued in this connection.
- b. "Owner" shall mean HLL Lifecare Limited, (Thiruvananthapuram) or its units thereof.
- c. **"Bidder**" shall mean the person, firm of Corporation submitting a bid against this Invitation for Bid and shall also include his agents and representatives.
- d. **"Supplier**" shall mean the bidder whose bid has been accepted and shall also include his successors and assigns, agents and representatives.
- e. **"Contract**" means signed acceptance of the Letter of Intend, if issued, and work order by the Contractor.
- f. "Site" means the Owner's manufacturing facility at Kerala.
- g. **"The bid documents**" in addition to the invitation for bids and Conditions of Bid (Schedule I), the bid documents include the following schedules.

SCHEDULE	-11	:	General Conditions of Contract
SCHEDULE	-111	:	User requirements
SCHEDULE	-IV	:	Price bid - Format for quoting

- h. **"Eligible Bidders**" This Bid is opened to all eligible manufacturers and/or their authorized agents.
- i. **"The contract price**" means the price payable to the Contractor under the contract for the full and proper performance of its contractual obligations.
- j. "Performance of the Contract" means successful completion of contract.

2. Bid Information and Period of Validity

- 2.1 Bidders shall submit their bids in two parts (TECHNICAL BID and PRICE BID)
- 2.2 The Technical Bid must include the following information;
 - a. The details specified under Technical bid Evaluation Criteria.
 - b. All other documents/certificate/information as specified in the bidding document.
- 2.3 The Price Bid must be as per the following
 - a. The bid is invited for "Supply, Installation, Testing and Commissioning of Automatic Two Line Sachet Packing Machines for personal lubricant at HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram" as per the Specification, Terms and Conditions as specified in the Bid Documents. The Bidder shall indicate the price in the enclosed format (Schedule IV) inclusive of all the consumables, relevant taxes and duties, other levies, insurance and other local costs, loading and unloading of Contractor's materials etc. on a turnkey basis as per the Specifications, Terms and Conditions, Schedule of Work specified in the Bid Documents. Civil work is excluded from the scope of the Contractor.
 - b. Rates should be firm without any escalation on any account till the order is completely fulfilled.
- 2.4 Bids shall remain valid for 90 days after the date of bid opening prescribed by the Owner.

3. Format and Signing of Bid

3.1 Bidders shall submit their bids in two parts (TECHNICAL BID and PRICE BID) as under.

- a) <u>Technical bids</u>, in duplicate clearly marking each "Original Bid" and "Copy Bid", as appropriate, consisting of the deviations in specifications if any, and also clause-byclause compliance of Technical Bid evaluation criteria, specifications and commercial terms and conditions and EMD, in separate sealed covers super scribing "Technical Bid" inside a main cover.
- b) <u>Price bids, in duplicate clearly marking each "Original Bid" and "Copy Bid", as appropriate, showing only item wise rates and total prices in separate sealed covers super scribing "Price Bid" inside a main cover.</u>
- 3.2 When the main cover is opened on the date and time scheduled for bid opening, only the technical bids will be opened.
- 3.3 Bidders whose technical bids are found substantially responsive will be informed of the date and time of opening of their price bids. Price bids of others will be returned to them unopened.
- 3.4 All pages of the bid, except for un-amended printed literature shall be signed by the person or persons signing the bid. The seal of the company shall be stamped in all pages.
- 3.5 Bids shall be made in English.
- 3.6 The bid shall contain no interlineations, erasures or overwriting except as necessary to correct errors made by the Bidder, in which case such corrections shall be signed by the person or persons signing the bid.

4. Submission of Bids

Sealing and Marking of Bids

- 4.1 The Bidder shall seal the original and each copy of the bid in an inner and then in an outer envelope, duly marked the envelopes as "original" and "copy".
- 4.2 The inner and outer envelopes shall be:
 - (a) Addressed to the Owner in the following address and

Deputy General Manager (CED) Central Engineering Division, HLL Lifecare Limited (A Government of India Enterprise), PB No 2, Peroorkada, Thiruvananthapuram – 695005, Kerala State, India Ph: (++91 471) 2433374,2437270 – 501, 502 Tele Fax: (++ 91 471) 2432647 E-mail:, rajeevrv@lifecarehll.com,

- (b) Bear the Enquiry No, closing date and General description of item tendered, and the words "DO NOT OPEN BEFORE" 15.30 Hrs (IST) on 21.06.2017 (Indicate the Closing Date).
- 4.3 The inner envelopes shall indicate the name and address of the Bidder. If the outer envelope is not sealed and marked as indicated above, the Owner will assume no responsibility for the bid's misplacement or premature opening.
- 4.4 Bids should be hand delivered or sent by courier to ensure timely receipt. Telex, Cable, Email or facsimile bids will be rejected.

Deadline for submission of Bids

4.5 The Owner in the following address will receive the bids not later than the date and time specified in the Invitation for Bids or Subsequent extended dates.

Deputy General Manager (CED) Central Engineering Division, HLL Lifecare Limited (A Government of India Enterprise), PB No 2, Peroorkada, Thiruvananthapuram – 695005, Kerala State, India Ph: (++91 471) 2433374,2437270 – 501, 502 Tele Fax: (++ 91 471) 2432647 E-mail:,rajeevrv@lifecarehll.com,

In the event of the specified date for submission of Bids being declared a holiday for the Owner, the bids will be received up to the appointed time on the next working day.

- 4.6 The Owner may, at his discretion, extend this deadline for submission of bids by amending the Bid Documents or any other reasons in which case all rights and obligations of the Owner and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.
- 4.7 It is the responsibility of the bidders to see that the completed bidding documents whether sent by post or by courier or by person are received in the **Office of the Deputy General Manager (CED) Central Engineering Division)**, in the above address by the date and time stipulated for receipt as above failing which the bid would be considered late and rejected. Owner will not be held responsible for the postal delay, if any, in the delivery of the bidding document or the non-receipt of the same. Bids received after due date and time will be rejected. Mere handing over of the bid documents at reception counter or at any other counter or room or person cannot be considered as submission of bid.

5. Clarification of Bidding Documents

1. A prospective Bidder requiring any clarification of the Bidding Documents may notify the Owner in writing, or by fax at the Owners mailing address indicated in the Invitation for Bids. The Owner will respond in writing to any request for clarification of Bidding Documents, which it receives not later than 7 days prior to the deadline for submission of Bids prescribed by the Owner.

6. Amendment of Bidding Documents

- 6.1 At any time prior to the deadline for submission of bids, the Owner may, for any reason, modify the Bidding Documents by amendment.
- 6.2 The amendment will be notified in writing or fax or telegram or e-mail to all prospective Bidders, which have received the Bidding Documents and will be binding on them.
- 6.3 In order to afford prospective Bidders reasonable time in which to take the amendment in to account in preparing their bid, the Owner may, at its discretion, extend the deadline for the submission of bids.

7. Bid Opening by Owner

7.1 The Owner will open bids, in the presence of the bidders' representatives who choose to attend, at the date and time specified and in the location given in this document. The Bidders' representatives who are present shall sign a register evidencing their attendance. In the event of the specified date of bid opening being declared a holiday for the Owner, the bids shall be opened at the appointed time and location on the next working day.

- 7.2 The Bidders' names, the presence or absence of the requisite EMD and such other details as the Owner, at his discretion, may consider appropriate will be announced at the opening.
- 7.3 The Owner will prepare appropriate bid opening register and bidders present during the opening of the bids and Owner shall sign the same.

8. Clarification of bids

To assist in the examination, evaluation and comparison of bids, the Owner may, at his discretion, ask the bidder for a clarification of its bid. The request for clarification and the response shall be in writing with a dead line date and no change in the price or substance of the bid shall be sought, offered or permitted.

9. Preliminary examination

- 9.1 The Owner will examine the bids to determine whether they are complete, whether any computational errors, have been made whether required EMD has been furnished whether the documents have been properly signed, whether the bid validity is as required and whether the bids are generally in order.
- 9.2 The determination will take into account the Bidder's financial, technical and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, as well as such other information as the Owner deems necessary and appropriate.
- 9.3 Prior to the detailed evaluation, the Owner will determine the substantial responsiveness of each bid to the bidding documents. For the purpose of these clauses, a substantially responsive bid is one which conforms to specifications and all the terms and conditions of the bidding documents without material deviation. The Owner's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.
- 9.4 A bid determined as not substantially responsive will be rejected by the Owner and may not subsequently be made responsive by the bidder by correction of the non-conformity.
- 9.5 The Owner may waive any minor informality or non-conformity or irregularity in a bid, which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any bidder.
- 9.6 The Owner's determination as to the substantial responsiveness or otherwise of each bid or consideration of a minor informality or non-conformity or irregularity is final and conclusive.

10. Evaluation and comparison of bids.

10.1 The Owner will technically evaluate all bids previously determined to be responsive and open the price bids previously determined to be substantially responsive and technically acceptable with intimation.

11. Post-qualification

- 11.1 Notwithstanding the qualification requirements given in this document, the Owner will determine to its satisfaction whether the Bidder selected as having submitted the lowest evaluated responsive bid is qualified to satisfactorily perform the Contract.
- 11.2 Arithmetical errors will be rectified on the following basis. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be calculated. If there is a discrepancy between the words and figures, the amount in words shall prevail.

- 11.3 The Owner reserves the right to negotiate with the lowest evaluated responsive bidder.
- 11.4 An affirmative determination will be a prerequisite for award of the Contract to the Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Owner will proceed to the next lowest evaluated bid to make a similar determination of that bidder's capabilities to perform satisfactorily.

12. Award Criteria

The Owner will award the Contract to the successful Bidder whose bid has been determined to be substantially responsive and has been determined as the lowest evaluated bid provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily for the items offered.

13. Notification of Award

- 13.1 Prior to the expiration of the period of bid validity, the Owner will notify the successful Bidder in writing by or cable or telex or fax, to be confirmed in writing by post, that its bid has been accepted. The notification of award may be sent in the form of Letter of Intend and/or Supply order.
- 13.2 The signed acceptance of the notification of award & execution of agreement in the format attached on proper stamp paper by the Contractor will constitute a concluded contract.
- 13.3 Upon the successful Bidder's furnishing of Security Deposit, the Owner will discharge EMD submitted by unsuccessful bidders.

14. Earnest Money

- 15.1 Each bid must be accompanied by E.M.D.
- 15.2 The EMD is required to protect the Owner against risk of Bidder's conduct, which would warrant the security's forfeiture
 - a. The EMD shall be in the form of Demand Draft from a nationalized bank drawn in favour of HLL Lifecare Limited, Thiruvananthapuram payable at Thiruvananthapuram.
 - b. E.M.D. of the unsuccessful bidders will be released after tabulating tenders, keeping only the earnest money of the first three lowest bidders. The earnest money deposit of the remaining two unsuccessful bidders will be released after the acceptance of the notification of award by the successful bidder.
 - c. In the case of successful bidder, the Earnest Money will be returned after the supply of material at HLL site.
- 15.3 The EMD may be forfeited:
 - a. If a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bidding Document; or
 - b. In case of the successful Bidder, if the Bidder fails:
 - i. to sign the Contract
 - ii. to furnish security deposit

SCHEDULE - II

GENERAL CONDITIONS OF CONTRACT

1. PROJECT INFORMATION

The detailed information of the project given below is as per Owner's present requirement. However, it is not binding on the Owner in any way and shall not govern the scope of works.

2. LOCATION

The machines to be installed in HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram.

3. PRICE

Price quoted should be firm without any escalation till the order is completely executed and should be for complete Supply, Installation, Testing and Commissioning of Automatic Two Line Vertical Form Fill Seal Sachet Packing for personal lubricant at HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram on a turnkey basis as per the terms and conditions of this bidding document.

4. TAXES / DUTIES / LEVIES

The rates quoted for each item should be inclusive of all applicable taxes and duties and any other levies for the successful Installation, Integration and Commissioning of the packing machines.

5. ESCALATION

The rates quoted by the Contractor in the contract documents shall be final and shall not be subjected to any change due to the increase in labour wages or inflation in the cost of materials or any other price variations due to any reason during the stipulated time period of the contract or during the extended time period of completion.

6. PAYMENT TERMS

The payment terms are as follows:-

- a) 50% of the payment shall be released after FAT and supply, of Two Line Vertical Form Fill Seal Sachet Packing machine at HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram-5.
- b) Balance 40% of the payment shall be released successful SAT ,installation ,testing and commission for 15 days of satisfactory continuous operation for 2 shift operation/days (16 hrs) / 15days validation, performance evaluation in terms of quality, quantity and commissioning, and final acceptance certificate issued by the competent authority.
- c) The balance 10% payment shall be released against a Performance guarantee valid for a period of one year from the date of the issue of final acceptance certificate of the entire system.

Tax Deduction: All statutory deductions like Service tax, Income Tax, E.S.I., P.F. or any other government imposed liabilities for this contract shall be borne by the Contractor (as applicable at the time of execution of job) and shall be deducted from each bill submitted by the Contractor.

Owner will not entertain the presentation of documents through Bank.

7. DEFECT LIABILITY PERIOD

The defect liability period of the work shall be 12 months from the date of completion of the SITC of machine and this date will start from successful completion and handing over. If any damage or defect occurs in the work during this period then the Contractor shall rectify the damage or defect at his own expense to the satisfaction of the Owner .If the Contractor fails to do so, then the Owner shall have the authority to get the work done by other means and the expenditure incurred shall be recovered from the Contractor.

Even if Inspection and/or tests are fully carried out by Owner or their representatives, the Contractor is not absolved to any degree of his responsibility to ensure that all equipment supplied comply strictly with the requirements as per specifications given in the order, and the Owner shall be free to point out any defect till the defect liability period is over.

8. PERIOD OF COMPLETION

The machines should be successfully commissioned at Owners site within **TWO MONTHS** from the date of notification of award.

Time being the essence of the Contract, the completion period stipulated should be strictly adhered to. Delay in erection and commissioning of the equipment will cause loss and/or damage to Owner. The completion period shall be counted from the date of sending of Owner's intimation of acceptance of the Contractor's offer (Letter of Intent (LOI) and/or Work order).

The equipment should be erected, tested, commissioned and handed over to Owner strictly within the time stipulated.

11. LIQUIDATED DAMAGES FOR DELAYS

If the equipment is not erected, commissioned and handed over to the Owner within the time stipulated in the Order, Owner may at their option, either (1) recover from the Contractor liquidated damages at the rate of 0.5 % of the total contract value for every week of delay, subject to a maximum of 7.5 % of the total contract value, or (2) at the risk and cost of the Contractor and without prejudice to the other remedies/rights as per the Contract, terminate the order wholly or partially and complete it themselves or reassign it to other contractors.

12. SETTLEMENT OF DISPUTES

Any disputes or differences or questions or claims arising under or relating to or touching this agreement shall be referred for arbitration to a Sole Arbitrator under the provisions of the Arbitration and Conciliation Act 1996 or any statutory modification or re-enactment thereof for the time be in force. The award passed by the arbitrator shall be final and binding on the parties hereto.

The contract shall be deemed to have been concluded at Thiruvananthapuram, Kerala and suits and proceedings, if any, shall be only in the courts of competent jurisdiction in Thiruvananthapuram.

The venue of arbitration shall be the place from where the contract is issued.

13. Change in specifications:

If there is any variation in specification or any change in make of item, then it has got to be approved from the Owner prior to installation or execution.

14. Inspection and testing

- a) System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.
- b) Vendor shall prepare FAT and SAT protocol and get approved from Clientc) Minimum 3 days shall be reserved for FAT and SAT each and vendor shall ensure
- the availability of relevant personnel test material and measurement devices.

SCHEDULE III

User Requirement Specifications – Two line sachet packing Machine Equipment ID: TSP-CED-001

1.0 OVERVIEW

- 1.1 PROJECT STANDARD
- 1.2 EQUIPMENT DESCRIPTION
- 1.3 REFERENCE STANDARDS/GUIDELINES FOR EQUIPMENT

2.0 PRODUCTIVITY REQUIREMENT

- 2.1 PRODUCTIVITY REQUIREMENT
- 2.2 CLEANING TIME (IF APPLICABLE)
- 4

3.0 SAFETY REQUIREMENT

- 3.1 GENERAL
- 3.2 POWER FAILURE AND RECOVERY

4.0 GMP REQUIREMENTS

4.1 PROCESS CONTROL

5.0 FAILURE MODE DETECTION

- 5.1 EQUIPMENT SHALL BE CAPABLE TO DETECT THE FOLLOWING FAILURE, NOTIFY THE OPERTOR WITH ALARM AND SHUTDOWN THE PROCESS
- 5.2 Emergency stop
- 5.3 LOW COMPRESSED AIR

6.0 LEVEL OF INSTRUMENTATION

- 7.0 CLEANING REQUIREMENT
- 8.0 QUALIFICATION REQUIREMENT
 - 8.1 GENERAL
- 9.0 MATERIAL OF CONSTRUCTION
- 10.0 USE OF LUBRICANTS
- 11.0 DATA INTEGRITY
- 12.0 DESIRED DOCUMENTS
- 13.0 TRAINING
- 14.0 TECHNICAL REQUIREMENT
- 15.0 LEVEL OF AUTOMATION
- 16.0 GOOD ENGINEERING PRACTICES REQUIREMENTS
- 17.0 INSPECTION AND TESTING
- 18.0 CONSTRAINTS

1.0 OVERVIEW

HLL Lifecare Limited is a public sector undertaking under the Ministry of Health and Family Welfare. It was incorporated in 1966 with the primary goal of producing quality condoms for the National Family Planning Program. HLL continues to be a leader in manufacturing condoms and contraceptives in India. HLL had since diversified into the manufacturing of other healthcare products such as Blood Bags, Surgical Sutures etc.

HLL in its quest to become a comprehensive healthcare player, proposed to set-up an Engineering excellence department for the fabrication of machines indigenously to cop up future machine demands in various manufacturing units..

For this purpose HLL has decided to engage Central Engineering Division to manufacture a Of Automatic Two Line Vertical Form Fill Seal Sachet Packing machine for personal lubricant, which compiles all the statutory requirements.

1.1 PROJECT STANDARD

The facilities, upon completion, shall be in compliance with the Indian FDA (Schedule R), WHO, USFDA, and EUGMP and also the HLL's internal quality standards.

1.2 EQUIPMENT DESCRIPTION

Two line sachet packing machine shall be used for personal lubricant packing. Two line Sachet Packing machine consists of a form fill and seal mechanism. Personal lubricant will be fed into the sachet formed by forming of the foil laminate, filling of the personal lubricant and sealing the sachet.

The machine is supported on main frame made up of SS structures, which has the capability to withstand the dynamic loads.

The overall design ensures a dust free operation and automatic to obtain satisfactory packs.

The machine will be controlled by the control system of the equipment.

1.3 REFERENCE STANDARDS/GUIDELINES FOR EQUIPMENT

The equipment should comply with the following guidelines / standard:

GMP-Regulations

- EU-GMP-Guideline
- CGMP in Manufacturing, Processing, Packing.

2.0 **PRODUCTIVITY REQUIREMENT.**

SI No	Specifications	
		Remarks
2.1	Productivity Requirement	Essential
2.1.1	Desired/ suggested capacityMinimum 80 sachets /	Essential
	minute (2line x 40 packets per min)	
2.1.2	Size of pack – 57x55 mm format.	Essential
2.1.3	Change Over Time (if applicable)	
		Optional
	Vendor to give information on change over time from one	
	product to another product	
2.2	Cleaning Time (if applicable)	
2.2.1	The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment	
2.2.2	Equipment contact parts shall be easily dismantable and cleanable.	

3.0 SAFETY REQUIREMENT

SI No	Specifications	
		Remarks
3.1	General	
3.1.1	In the event of equipment malfunction or loss of utilities,	Essential
	the unit must contain all necessary protection devices to	
	ensure that the equipment and the article remain in a	
	safe condition	
3.1.2	Noise level below 75 db at a distance of 1 m from the equipment	Essential
3.1.3	Emergency stop function on all accessible areas	
3.1.4	Appropriate failure detection and alarm notification	
3.1.5	Appropriate closure of all the rotating parts	
3.1.6	Interlocking with limit switch	
3.1.7	Proper earthing of the equipment	
3.2	Power failure and recovery	
3.2.1	On power failure equipment shall come to rest, to	
	protect operator, equipment itself and the product.	

3.2.2	Power restart must not be automatic and human	
	intervention must be required	
3.2.3	After regain of power the equipment should start from the	
0.2.0		
	step it stopped	

4.0 GMP REQUIREMENTS

SI No	Specifications	Remarks
4.1	Process control: The equipment must operate and control the following process parameters.	
4.1.1	Speed of the Machine	
4.1.2	Sealing temperature	
4.1.3	Personal lubricant dosing quantity	

5.0 FAILURE MODE DETECTION

SI No	Specifications	Remarks
5.1	Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process	
5.2	Emergency stop	
5.3	Low compressed air	
5.4	Less lubricant liquid pressure	

6.0 LEVEL OF INSTRUMENTATION

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

Type of control	Purpose	Instrumentation	Remarks
Speed of the machine	To monitor & Control the speed of the machine	Tachometer	
Empty foil sensor	To sense the empty foil as soon as it reach empty	Sensor with alarm	
Personal lube oil dosing	To monitor the quantity of personal lube oil	Timer and pressure	

	L	_evel of lubricant	To monitor the level of lube oil	Level sensor	
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7.0 CLEANING REQUIREMENT

7.1 All bolts, nuts on the exterior part of equipment will be with cap head or cap nut.

7.2 Design of equipment should enhance cleaning feasibility by providing minimum sharp corners, minimum

Crevices & smooth finished welds joints.

7.3 The equipment shall be compatible to different cleaning agents

8.0 QUALIFICATION REQUIREMENT

8.1 General

- 8.1.1 Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) and the performance phase (PQ).
- 8.1.2 Vendor shall support client in execution of all the qualification phases.

9.0 MATERIAL OF CONSTRUCTION

- 9.1 All following metallic critical contact surfaces should be constructed of 316L grade stainless steel or better with internal mirror surface finish < 0.5μm Ra and external surface finish matt finish < 1.2μm Ra.</p>
 - a) Surfaces coming in direct contact of product
- 9.2 All non-product contact metallic surfaces should be constructed of 316 grade stainless steel or better, external surface finish as matter finish
 1.2µm Ra.

9.3 All welds should be ground finished to $< 1.2 \mu m$ Ra and properly passivated

10.0 USE OF LUBRICANTS

10.1 Any lubricant, used in the equipment must be of food grade and non-toxic.

11.0 DATA INTEGRITY (Optional)

11.1 System security shall be provided to access the operating system and configurable parameter values through access password. 3 level accesses shall be preferred

11.2 BATCH RECORD PRINTING (QUOTE AS OPTIONAL)

Equipment identification number	Remarks
Process code &/or identification (process program number)	
Program information and parameters	
Start date and time	
End date and time	
All failures and alarms	
Process record, preferably a real time graphical	
representation for important process controls parameters.	
Operator code and name	
There should be a possibility to store and archive the data for future retrieval	
Company logo in the report	

11.2.1 A complete batch record indicating the following important parameters in English language, but not limited to these:

11.2.2 The System shall include the following important parameters not limited to these:

11.2.2.1 Alarms.

11.2.2.2 Product information and set parameters (if applicable).

12.0 Desired documents

12.1 Phase 1: Preordering of the equipment

- 12.1.1 Filled in URS
- 12.1.2 Equipment layout drawing fitted in the room layout block
- 12.1.3 Detail technical offer that support the compliance of the URS

12.2 Phase 2: Post ordering and prefabrication stage of the equipment.

- 12.2.1 Functional design specification and technical specification, thatshould contain the following:
 - Equipment descriptions and its function
 - Equipment operation steps
 - List of failure indications
 - List of interlocks
 - List of input/outputs and its functions
 - Critical list of major component, devices and instruments with their specific functions, specifications data sheet
 - List of media contact surface and its MOC

•Schematic/GA diagram of the equipment

12.3 Phase 3: Fabrication stage of the equipment

12.3.1 Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.

12.4 Delivery of the equipment

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.

- 12.4.1 Operation and maintenance manuals, preventive maintenance schedule for equipment major component as well as the operating system.
- 12.4.2 Operation and maintenance manuals for the bought out items.
- 12.4.3 Installation instructions/ guideline for equipment.

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- 12.4.4 Final as-built drawing for equipment.
- 12.4.5 Spare and/ or change parts list with ordering information.
- 12.4.6 Weld verification reports.
- 12.4.7 Instrument calibration certificates with respect to the traceable national reference standard instrument and their calibration procedure.
- 12.4.8 Guaranty/ warranty certificates for each equipment and major boughtout items, such as PLC, printer, recorders, instrumentation etc.

13.0 Training

- 13.1 A special training for operators has to be included
- 13.2 A special training for technical staff has to be included

14.0 Technical requirement

14.1 Basic technical requirement

14.1.1 A proposal of a possible installation layout should be added to the documentation.

14.1.2 The manufacturer has to give the clear details on the total weight and the capacity of the equipment.

14.1.2 The construction of the complete system should be described in the documentation in detail.

14.1.3 All revolving parts should be mounted on antifriction thrust bearings.

14.1.4 All the required conditions and data values are displayed on the touch screen.

14.1.5 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor.

- 14.1.6 Vendor shall provide special tools for maintenance of the equipment.
- 14.1.7 Space below the equipment shall be six inches for the accessibility of cleaning.
- 14.1.8 Supply of two line sachet packing machines capable of foil sealing with automatic silicon oil dosing quantity from 3ml to 20ml plc based automation
- 14.1.9 size of pack 57x55 mm format
- 14.1.10 Multiposition pneumatic cutting with zig zag perforation at single point, programmable cutting 1, 2,3,4,5,6,7,8,9,10. Cutting unit.(**Perforation** Single point cutting and perforation is equipped with modified cutting unit)
- 14.1.11 Automatic stopping system for foil finishing in the loaded reel.
- 14.1.12 Pneumatic pump 2 lanes for dozing personal lubricant in the range of 3ml to 20ml Accuracy +-0.5ml
- 14.1.13 Automatic stopping system for foil finishing in the loaded reel.
- 14.1.14 Sealing temperature interlock system.
- 14.1.15 Oil detection system (no-lub alarm).
- 14.1.16 Sealing jaw
- 14.1.17 The works involved are inclusive of suitable design, integration, and synchronization of the system to fulfill two line square format with different materials of foils.
- 14.1.18 Drive system: it consists of direct driven motorized gearbox solid shaft type with suitable out put rpm connected to the main shaft through roller chain/standard/latest method drives with suitable roller chain sprockets and also able to drive the sealing rollers, slit cutters and the pulling system etc to match the linear speed of the foil movement.

- 14.1.19 Foil release mechanism: foil feeding should be with most efficient mechanical drive with standard energy efficient engg transmission method with eye mark control.
- 14.1.20 Material of construction: all the other parts of the machine body should be with SS 304 to avoid rusting during running and periodical painting expenses. the material used in the paths and contact parts should be perfectly in conformance to eliminate handling damage to the natural rubber product and as per WHO,GMP standards. Standard engineering materials should only be used in the case of other components like gears, bushes locks used for the mechanism used in the integration of the system with accessories. All the specifications are given in the relevant drawings of parts.
- 14.1.21 Cutting and perforation: pneumatic cutting with single station cutting and perforation is to be used. The specification and cutting unit with plc controlled cutting selection with eye mark control.
- 14.1.22 Foiled strip movement: proper chute arrangements are to be provided for the discharge of foils at the rate of 80 pcs per minute.
- 14.1.23 PLC control system: all the components like sensors, timers, motor controllers, temperature controls, temperature switches, solenoid operated valves, wiring and hardwares and softwares will be incorporated to carry out the complete feeding and foiling process. process parameters setting
- 14.1.24 All controllers should be suitable for withstanding power fluctuations and with soft starting technology. Pneumatic control valves and other actuators are to be of suitable design with the space limit mentioned.
- 14.1.25 Necessary painting/powder coating works suitable for dusty and hot environment as per standard norms. Suitable sensing and control system should be provided for completing the process starting from foil feeding, oil feeding, foiling and cuttings. Static electricity dischargers should be provided wherever necessary.
- 14.1.26 Rate should be quoted separately for supply and installation like integration, testing and commissioning of one such system as per price schedule.& Bill of materials should be provided separately in support to the supply.
- 14.1.27 Commissioning: commissioning of the system or any part thereof shall be commenced by the bidder immediately after receipt of intimation from HLL. HLL shall supply the operating personnel and all raw materials, utilities, lubricants, chemicals services and other matters required for commissioning.
- 14.1.28 Performance test: the performance test shall be conducted by the

bidder during the commissioning of the system to ascertain whether the system can attain the functional guarantees specified in the technical specification.

- 14.1.29 Operational acceptance: operational acceptance shall occur in respect of the system when the performance test has been successfully completed and the functional performances are met.
- 14.1.30 Period of warranty shall be 12 months from the date of installation and commissioning as certified jointly by the supplier and the purchaser.
- 14.1.31 The bidder shall attend the pre-bid conference if any arranged by HLL
- 14.1.32 Three copies of instruction/operational manual (especially for brought out items) and maintenance manual should be supplied along with the machine.
- 14.1.33 A list of spare parts should be provided. a minimum set of spare parts should be provided for each machine.
- 14.1.34 Brought out items such as electrical/electronic items, electric heat banks etc should be as per relevant Indian standards approved certifications.

15.0 Level of automation

15.1 The equipment should operate with minimum operator involvement. The equipment control panel must be provided with PLC.

	Proposed Specification for Sachet packing machine f	or Personal Lubricant.		
1.	Packing Material			
	Sachet Laminate Structure (Specification) 4 Ply	1.9 – 12.1 micron PET with reverse printing / 18 - 20 micron Poly / 8.28 – 9.72 micron Aluminium (Dull i.e. matt side on top / Minimum 25 micron Surlyn 1652 SR (Coating on the bright side).		
2	Material to be packed .Lubricant viscosity and type	GEL:shall have a viscosity between 200 and 350 centistokes, and water-based.		
3	Sachet (Dimension)			
	Length (mm)	57		
	Width(mm)	55		
	Sachet (Sealing) Type	4 side sealing		
4	Packing Machine Features	Vertical volumetric form fill seal machine		
	No: of Tracks	2		
	Speed	40X 2 = 80 Sachet per minute minimum per machine		
	Dosing Capacity (Packing volume)	3ml to 20ml Accuraccy +-0.5ml		
	Stainless steel parts SS 304 including the construction of non contact parts.Product contact parts SS 316 Double head stainless steel 316 adjustable dosing pump.(injection syringe type) suitable for dosing personal lubricant in the volume range 15ml with adjustable stroke with FESTO/CRD/SMC pneumatic cylinders to provide the lateral movement synchronised with			
	Hopper capacity	Minimum 30 litres		
	Sealing mechanism	Pneumatic		

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	PLC Controlled	
	Film draw mechanism	By servo motor
	PLC Controlled Electronic Packing Machine control device sachet length, eyemark tracking for print correction, indication count, temperature settings and mach	on lamps, display of total sachet
	Batch coding Embossing typ	e
	Siemens/Schneider/ABB variable speed drive for co	ntrolling packing speed.
	Jogging switch to aid in machine setting	and cleaning
	PID Temperature controller preferably Omron/Fuji/Mithsubu PLC	schi/AB Make integrated into the
	PLC integrated warning device cum indicator for vertical an stop in case of heater burnou	
	PLC integrated warning device cum indicator for low proc buzzer	luct level with auto - stop and
	PLC integrated warning device cum indicator for end of f	Im with auto stop and buzzer
	Easy tear notch to be provide	d
	Max web width of roll mm	600
	Max roll dia. mm	450
	rubber parts	silicon rubber
5	4 Side Seal Rejoice Rejoice Rejoice Rejoice	

SCHEDULE IV

PRICE BID

FORMAT FOR QUOTING

Schedule for the Supply, Installation, Testing and Commissioning of Automatic TWO LINE VERTICAL FORM FILL SEAL Sachet Packing Machines for Personal Lubricant at HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram

SI.No.	Description of Item	Unit	Quantity	Rate in Rs.	Amount in Rs.
1	Supply of Automatic Two Line Sachet Packing Machines for personal lubricant at HLL Lifecare Limited Peroorkada Factory, Thiruvananthapuram	No	1.00		
2	Installation, Testing and Commissioning charges of Automatic Two Line Sachet Packing Machines for personal lubricant.	No	1.00		
	Basic price in Rs.				
	Packing & Forwarding charges Rs.				
	CST in Rs.				
	Freight charges in Rs.				
	Other taxes/Charges any in Rs.				
	Gross Amount in Rs.				

(In words)

I agree to supply all the items as per schedule at the rates quoted by me as above and the terms and conditions of the tender document.

SIGNATURE OF THE SUPPLIER