TENDER DOCUMENT (Not Transferable)

"Tender for empanelment of Analytical laboratories accredited by "National Accreditation Board for Testing and Calibration" (NABL) for the analysis of samples of drugs for a period of 1 year"

Tender No. HLL/CHO/CQA/SDT/1 -2015 dated 15.07.2015



HLL Lifecare Limited HLL Bhavan Poojappura Thiruvananthapuram-695012 Kerala

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NOTICE INVITING TENDER

Tender No. HLL/CHO/CQA/Tender/208 -2015 dated 08.07.2015

We, HLL Lifecare Ltd (formerly Hindustan Latex Ltd.) a Govt. of India enterprise, under the MOH&FW is engaged in the business of contraceptives, medical devices, health care products and pharmaceutical drugs, procurement services, diagnostics services, infrastructure services etc.

We invite bids from interested parties for laboratory testing of HLL branded pharmaceutical drugs (attached as Annexure A) under rate contract for a period of one year.

A. Test Requirements

- 1. The analysis will be carried out as per Pharmacopoeial monographs with the use of Pharmacopoeial Reference Standards. In case of non pharmacopoeial methods the laboratory can use methods that are validated as per ICH guidelines.
- The tests* required are Description, Identification, Uniformity of Weight, Dis integration time, Dissolution and Assay test.(*may vary based on the dosage form)

B. Qualification Criteria/Requirements

1. The Analytical Testing Laboratory should be accredited by "National Accreditation Board of Laboratories" (NABL) and such accreditation should be valid on the date of submission of Tender. Bidder should submit copy certificate of Accreditation issued by NABL (duly certified by a Chartered Accountant) for Chemical/ Biological testing including testing of drugs and medical supplies as the case may be.

2. The Analytical Testing Laboratory should have approval under the Drugs and Cosmetics Act, 1940 (including its amendments) and should comply with Schedule L-1 of Drugs and Cosmetic Act. A valid document issued from regulatory authority in support of this should be provided.

3. Analytical Laboratory, which has manufacturing activity, shall not be eligible to participate in the tender. Agents of Analytical Testing Laboratories are not eligible to participate in the tender.

C. Terms and Conditions:

- 1. The Bidder should submit Price Bid by giving the rate of Testing Charges for the *complete analysis of "single sample" of an item* and not for individual tests to be performed on the sample.
- The rates quoted should be inclusive of all taxes but exclusive of service tax. The Service tax as per prevailing rate shall be paid to the Laboratory upon submission of claim and proof of Service Tax Registration.
- 3. The rates quoted and accepted will be binding on the bidder for the stipulated period and on no account any revision will be entertained till the completion of the contract period.
- 4. Bidders are requested to submit their bid following the requirements mentioned in Annexure D with all documents in a sealed envelope super scribing "Tender for laboratory testing of drugs" on the envelope.
- 5. HLL reserves the right to conduct the inspection of the laboratory facility if needed as part of technical evaluation and bidders must facilitate the same on request and HLL reserves the right to technically disqualify any bidder if found technically incompetent.
- 6. HLL will send the samples required for testing to the lab under our own expense and the receipt of the same should be confirmed by return mail.
- 7. The bidder should send the hard copy of the test results along with the invoice to the undersigned within 15 days after receipt of the

samples. The soft copy of the test result may be shared with HLL Lifecare Ltd to the below mentioned email id within 10 days of receipt of samples at your end.

- 8. For any delay more than the time stipulated above as the case may be, 1% of the testing charges per week and the part there of would be deducted as penalty. If consecutively delayed for 4 times or more than 8 times in a year, then the penalty for subsequent delays would be 2% of testing charges per week and part thereof.
- "COMPLIES" or "PASS" in the result column of the report is treated as incomplete report, if the result has some value. Every test report must have specific remarks (i.e.) Standard Quality or Not of Standard Quality.
- 10. 100 % payment shall be released only after the receipt of signed test report/COA and invoice for the testing from the respective laboratory and will be through RTGS online transfer only. The payment will be affected within a period of 30 days from the receipt of invoice.
- 11. HLL shall enter in to a rate contract for a period of one year with the empanelled bidders.
- 12. HLL shall place work orders for the empanelled bidders as and when requirement arises during the tenure of the contract. The estimated testing requirement (till March, 2016) is given in Annexure A but the testing quantity may be changed by HLL Lifecare Ltd as and when required.
- 13. In case of failure of a sample, the result should be communicated immediately to the undersigned or his representative through phone / E-mail and the report should be sent with protocols.
- 14. If any sample is received in a damaged condition by the laboratory, the sample should not be analyzed and the information should be sent immediately to the undersigned or his representative through phone / E-mail.
- 15. Violation of any tender or empanelment conditions will disqualify a laboratory to participate in the tender for the next 5 years.

- 16. To assess the correctness of the test results being given by the Empanelled laboratories, at random, HLL Lifecare Ltd can exercise the option of witness testing by its authorized representatives from the residual sample or alternatively the residual samples may be sent to the Government Analyst for testing and if any variation is found the result would be informed to empanelled laboratories. If there is any variation in the test data more than 5% in the analytical reports furnished by the empanelled laboratories (either pass or fail) with the Government Lab for 3 times in assay test and 4 times for other than assay, in a year, the empanelled laboratory will be blacklisted for a period of 5 years after following the due process.
- 17. If it is revealed that the analytical Laboratory is involved in any form of fraud in testing process, the bidders shall be liable for action under criminal law and the matter will be notified to the concerned Director of Drugs Control for penal action against them.
- 18. HLL Lifecare Ltd will be at liberty to terminate empanelment without assigning any reasons. The bidder will not be entitled for any compensation whatsoever in respect of such termination.

D.DOCUMENTS REQUIRED FOR PARTICIPATION IN THE TENDER

The bid of the bidders shall constitute all documents mentioned in Annexure D of the tender. HLL will only consider the bidders submitting all the required documents mentioned in Annexure D.

E. EVALUATION & ACCEPTANCE OF TENDER

- 1. The bids will be opened at 15.00 hrs on 30.07.2015 and taken up for evaluation.
- 2. Technical Evaluation of the bids will be done & awarding the testing work shall be based on the product wise competitive rates for the L1 bidder.
- The L-2 and L-3 bidders will be invited to match the rate quoted by the L1 Bidder.

 In case, L-2 and L-3 agree so, they shall also be empanelled and the testing work may be awarded to them on need basis as required by HLL Lifecare Ltd.

F. AMENDMENT OF BID DOCUMENTS

- 1. At any time, prior to the date of submission of Bids, HLL may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective bidder, modify bid documents by amendments.
- 2. The amendments shall be notified in the website of HLL only and these amendments will be binding on the bidder.
- 3. In order to afford prospective bidders a reasonable time to take the amendment into account in preparing their bids, HLL may, at its discretion, extend the deadline for the submission of bids suitably.

G.Earnest Money Deposit (EMD)

- The bidder shall furnish, as part of his bid, for an amount of Rs.5,000/-(Rs. Five thousand only) as EMD in the form of DD drawn in favor of HLL Lifecare Limited, payable at Trivandrum.
- 2. EMD of the successful bidder (L1) will be treated as security deposit and will be returned after the successful completion of the contract period.
- 3. EMD of the unsuccessful bidders and other empanelled bidders (L2 & L3) will be returned as promptly as possible as but not later than 30 days after the signing of the contract with the L1 bidder.

H.HLL'S RIGHT TO ACCEPT ANY BID AND TO REJECT ANY OR ALL BIDS.

HLL reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids, at any time prior to award of contract without assigning any reason whatsoever and without thereby incurring any liability to the affected bidder or bidders on the grounds of purchaser's action.

Your sealed offer (all documents mentioned in Annexure D) against the above should reach us on or before 30.07.2015, 14.30 PM and the same shall be opened at 15.00 pm on the same day at our Registered &Corporate Office HLL Bhavan, Poojappura, Thiruvananthapuram- 69501 2, Kerala.

In case of any query, please contact the undersigned.

For HLL Lifecare Ltd R. Jayashankar Deputy General Manager (CQA) & MR HLL Lifecare Ltd, Poojappura, Thiruvananthapuram-695012. Ph: 0471-2350065, Email id: <u>rjayasan@lifecarehll.com</u>

Annexure A (List of Products for testing)			
S1 No	Product	Unit of Measurement (UOM)	Estimated no of batches for testing till March, 2016
1	Aceclofenac 100mg + Paracetamol 325mg + serratiopeptidase 15mg	1 Strip of 10 tablets	1
2	Ambroxyl 15mg + guaiphenisin 50mg + Terbutaline 1.25mg + Menthol 0.5mg/5ml	100ml syrup	
3	Amoxycillin 250mg + Clavulanic acid 125mg tabs	6 tabs/strip	5
4	Amoxycillin 500mg + Potassium Clavulanate 125mg tabs	10 tabs/strip	5
5	Azithromycin 500mg tabs	3 tabs/strip	3
6	Calcium Orotate 740mg	1 Strip of 10 tablets	3
7	Cefixime 100 mg DT Tabs	10 Tabs. / Strip	1
8	Cefixime 200mg mouth dissolving tabs	10 tabs/strip	3
9	Cefixime 50mg/5ml dry syrup	30ml bottle	5
10	Cefpodoxime 100 mg Clavulanic Acid 62.5 mg DT Tabs	6 tabs/strip	3
11	Cefpodoxime 100 mg DT Tabs	10 tabs/strip	1
12	Cefpodoxime 200 mg Clavulanic Acid125 mg Tabs	6 tabs/strip	3
13	Cefpodoxime 200 mg Tabs	10 tabs/strip	1
14	Cefpodoxime 50mg dry syrup	30ml bottle	5
15	Elemental Calcium 250mg with Vitamin D3 Tablets	Strip of 15 tabs	1
16	Elemental Calcium 500mg with Vitamin D3 Tablets	Strip of 15 tabs	5
17	Ferrous ascorbateeq to 100mg iron+ folic acid 1.5mg + Zinc 22.5mg tabs	10 tabs/ strip	6
18	Fluconazole 150mg tabs	1 tab / strip	4

19	Folic acid 5mg + Methcobalamine 1500mcg + Pyridoxine HCl 1.5 mg + DHA 200mg	10 tabs /strip	2
21	Grapeseed extract 25mg + Co enzymeQ10 + Lycopene 2 mg+ Lutein 3mg + vit. A 5000IU+ vit B1 5mg + vit B2 5mg+ vit B6 1.5mg + vit B12 15mcg + folic acid 1.5mg + zinc suplhate 23mcg + selenium dioxide 75mcg	10 tabs / strip	2
22	Inositol 600mg + Biotin 5mg + Elemental chromium 200mcg + folic acid 1.5 mg + Lycopene 5mg + NAC-300mg + Vit D3 1000 IU	m 200mcg + Lycopene 5mg 10 tabs/ strip	
23	Levocetrizine 5mg	Strip of 50 tablets	1
24	Micronized Dehydroepiandrosterone 75mg SR Tab	7 tabs /strip	1
25	Misoprostol 200mcg tabs	4 tabs/strip	3
26	Natural Micronised Progesterone 300mg SR tabs	10 tabs / strip	1
27	Natural micronisedprogestrone 100mg soft gel caps	10 caps/strip	3
28	Natural micronisedprogestrone 200mg soft gel caps	10 caps/strip	5
29	Norethisterone 5 mg tabs	10 tabs/strip	3
30	Ondansetron 2mg/5ml	30ml syrup	1
31	Ondansetron 4mg mouth dissolving tabs	10 tabs/strip	3
32	Rabeprazole 20 mg+Domperidone 30 mg caps	10 caps/strip	3

Annexure B

Details of the Bidder

- 1. (a) Name of Firm:
 - (b) Country of incorporation:
 - (c) Address of the corporate headquarters and its branch office(s), in India:
- (d) Date of incorporation and/ or commencement of business

2. Details of individual(s) who will serve as the point of contact/ communication for the Authority:

- (a) Name:
- (b) Designation:
- (c) Company:
- (d) Address:
- (e) Telephone Number (Mobile as well as Office):
- (f) E-Mail Address:
- (g) Fax Number:
- 3. Particulars of the Authorised Signatory of the Applicant:
- (a) Name:
- (b) Designation:
- (c) Address:

(d) Phone Number (Mobile as well as Office):

(e) Fax Number:

(f)	E-Mail	Address:
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5. Details of NABL Accreditation of the Lab (Attach copy of NABL accreditation of the firm):

Signature	:	Date :
Name	:	Place :

	Annexure C (Price Bid Submission Form)			
S1 No	Product Details	Unit of Measurement (UOM)	Price in INR (inclusive of all taxes)	
1	Aceclofenac 100mg + Paracetamol 325mg + serratiopeptidase 15mg	1 Strip of 10 tablets	S	
2	Ambroxyl 15mg + guaiphenisin 50mg + Terbutaline 1.25mg + Menthol 0.5mg/5ml	100ml syrup		
3	Amoxycillin 250mg + Clavulanic acid 125mg tabs	6 tabs/strip		
4	Amoxycillin 500mg + Potassium Clavulanate 125mg tabs	10 tabs/strip		
5	Azithromycin 500mg tabs	3 tabs/strip		
6	Calcium Orotate 740mg	1 Strip of 10 tablets		
7	Cefixime 100 mg DT Tabs	10 Tabs. / Strip		
8	Cefixime 200mg mouth dissolving tabs	10 tabs/strip		
9	Cefixime 50mg/5ml dry syrup	30ml bottle		
10	Cefpodoxime 100 mg Clavulanic Acid 62.5 mg DT Tabs	6 tabs/strip		
11	Cefpodoxime 100 mg DT Tabs	10 tabs/strip		
12	Cefpodoxime 200 mg Clavulanic Acid125 mg Tabs	6 tabs/strip		
13	Cefpodoxime 200 mg Tabs	10 tabs/strip		

14	Cefpodoxime 50mg dry syrup	30ml bottle	
15	Elemental Calcium 250mg with Vitamin D3 Tablets	Strip of 15 tabs	
16	Elemental Calcium 500mg with Vitamin D3 Tablets	Strip of 15 tabs	
17	Ferrous ascorbateeq to 100mg iron+ folic acid 1.5mg + Zinc 22.5mg tabs	10 tabs/ strip	
18	Fluconazole 150mg tabs	1 tab / strip	$\mathbf{}$
19	Folic acid 5mg + Methcobalamine 1500mcg + Pyridoxine HCl 1.5 mg + DHA 200mg	10 tabs /strip	S,
21	Grapeseed extract 25mg + Co enzymeQ10 + Lycopene 2 mg+ Lutein 3mg + vit. A 5000IU+ vit B1 5mg + vit B2 5mg+ vit B6 1.5mg + vit B12 15mcg + folic acid 1.5mg + zinc suplhate 23mcg + selenium dioxide 75mcg	10 tabs / strip	
22	Inositol 600mg + Biotin 5mg + Elemental chromium 200mcg + folic acid 1.5 mg + Lycopene 5mg + NAC- 300mg + Vit D3 1000 IU	10 tabs/ strip	
23	Levocetrizine 5mg	Strip of 50 tablets	
24	Micronized Dehydroepiandrosterone 75mg SR Tab	7 tabs /strip	
25	Misoprostol 200mcg tabs	4 tabs/strip	
26	Natural Micronised Progesterone 300mg SR tabs	10 tabs / strip	
27	Natural micronisedprogestrone 100mg soft gel caps	10 caps/strip	

28	Natural micronisedprogestrone 200mg soft gel caps	10 caps/strip	
29	Norethisterone 5 mg tabs	10 tabs/strip	
30	Ondansetron 2mg/5ml	30ml syrup	
31	Ondansetron 4mg mouth dissolving tabs	10 tabs/strip	
32	Rabeprazole 20 mg+Domperidone 30 mg caps	10 caps/strip	7

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Annexure D

Check List for the Bid

SL			Page No. in	
No.	Document	Yes/NO	the Tender	Remarks
			Document	
1.	Covering Letter			
2.	EMD (Demand Draft)			
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3.	Authorization Letter			
	nominating a responsible			
	person for business			
	transaction with HLL Lifecare			
	Ltd			
4	Technical literature/ Brochures			
5	Details of the Bidder			
	(Annexure B)	5		
6	Price Bid (Annexure C)			
7	Copy of NABL certificate duly			
	attested by a chartered			
	accountant			
8	Self-attested copy of			
	Certificate of Incorporation Of			
	the Firm			
9	Copy of Analytical License			
	under Rule 150(B) issued by			
	the Drugs Controller duly			
	attested by Chartered			
	Accountant.			

10	List of qualified personnel	
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	employed in the laboratory	
	along with qualification details	
11	List of sophisticated	
	instruments available in the	
	laboratory	
12	Self-attested copy of	
12		
	certificate of registration for	
	service tax	
13	Signed tender document	

Signature	:	
Name	:	
Date	00	
Place		