

NOT TRANSFERABLE



TENDER NO. :- BPPI/Surgical/Testing/19

**TENDER FOR EMPANELMENT OF ANALYTICAL
TESTING LABORATORIES FOR THE TEST AND ANALYSIS
OF DRUGS/SURGICAL ITEMS FOR 2015-2017**

Dated: 06.05.2015



BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

(Set up under the Department of Pharmaceuticals, Govt. of India)
IDPL CORPORATE OFFICE, IDPL COMPLEX, DUNDAHERA, GURGAON 122016
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BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA (BPPI)

(SET UP UNDER THE DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA)

Regd. Office: Core No. 6, First Floor, SCOPE Complex, Lodi Road, New Delhi-110003

Working Office: IDPL CORPORATE OFFICE, IDPL COMPLEX, DUNDAHERA, GURGAON (HR)

TENDER FOR EMPANELMENT OF ANALYTICAL TESTING LABORATORIES
FOR THE TEST AND ANALYSIS OF DRUGS/SURGICAL ITEMS FOR 2015-2017

Important Dates:	
Tender Reference Number	BPPI/Surgical/Testing/19 Date 06/05/2015
Date of availability of Tender documents on website	06/05/2015 (Wednesday)
Last date and time for receipt of Tender	27/05/2015 (Wednesday)15.00 hrs
Date and time of Opening of Tender	27/05/2015 (Wednesday)15.30 hrs
Place of Opening of Tender	BPPI, IDPL Corporate Office, IDPL Complex, Dundahera, Gurgaon (HR)
Address For Communication	BPPI, IDPL Corporate Office, IDPL Complex, Dundahera, Gurgaon (HR)-122016
Contact Person for clarification if any:	
1. Mr. D. K. Shringi, Phone: 0124-4556770, Mob: 9414054021 Email: dkshringi@gmail.com	2. Mr. Mahadev Agarwal, Phone: 0124-4556756, Mob: 9873294473 Email: mquality.janaushadhi@gov.in ;

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BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

(Set up under Department of Pharmaceuticals, Govt. of India)

TENDER FOR EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS/SURGICAL ITEMS FOR 2015-2017

“CONFIDENTIALITY IS THE ESSENCE OF THIS TENDER”

1. Sealed tenders are invited till 27/05/2015 Wednesday (15.00 hours) by **General Manager (A&F) at Bureau of Pharma Public Sector Undertakings of India (BPPI), IDPL Corporate Office, IDPL Complex, Dundahera, Gurgaon-122016 (Haryana), (Herein referred as Tender inviting authority unless the context otherwise requires)** for empanelment of approved drug testing laboratories (under Drugs & Cosmetics Act 1940 & Rules 1945) which are GLP compliant (as per Schedule L1) or NABL accredited for drugs requiring Chemical/Physico-chemical, instrumental, Pharmacological and microbiological testing facilities **for a period of two years** from the date of acceptance of tender by BPPI. The agreement may be extended for further period on mutually agreed terms.

The complete set of tender document can be downloaded from the BPPI website janaushadhi.gov.in and pharmaceuticals.gov.in free of cost.

NOTE:- LATE TENDER IS NOT ACCEPTABLE

2. Eligibility Criteria:

(a). Drug/Surgical Testing Laboratories should have valid Approval for carrying out test on Drug/surgical under the Drugs and Cosmetics Act, 1940 and Rules there under, with two years standing in the test and analysis of Drugs/surgical items with an minimum average annual turnover of Rs. 30 Lakhs for last two years (Govt./CPSU's Laboratories, Research and Development Laboratories, Laboratories run by Co-operative body and Educational Institutions are exempted from the turnover criteria) ***however turnover for the year 2014-15 should not be less than Rs. 30 lakhs, are eligible to participate in the tender.*** Agents are not eligible to participate in the tender. The lab shall be entitled for empanelment for the categories of items for which lab is having approval. Bid is invited from GLP compliant approved and NABL Accredited Drug Testing Laboratories situated in India.

(b). Drug Testing Laboratory which is also engaged in manufacturing of Drugs/Surgical and participate in drug/surgical procurement as well as drug/surgical testing Laboratory tender shall not be considered for testing laboratory empanelment as eligible if their product achieve L-1 rate in any drug/surgical procurement tender by BPPI.

(C). Drug/Surgicals Testing laboratories should have Approval/ license under Drugs & Cosmetics Act and Rules 1945 , with two years standing in the analysis of Drugs /Surgical Items.

(d). Drug Testing laboratories should be GLP compliant under the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 and should hold Schedule L1 certificate and should have NABL accreditation with proper scope of accreditation to undertake testing of drugs/surgical items.

(e). Drug/surgical Testing laboratories should not have been banned/debarred/ black listed/ Deregistered by any State or Central Govt. Organizations or its procurement agencies on the due date of bid submission.

(f). Drug/surgical Testing laboratory and its responsible persons should not have ever been convicted for any offence under the D & C Act 1940 and Rules 1945.

(g). Drug/surgical Testing laboratory should have all necessary instruments/equipments and required mandatory facilities for testing/analysis of Drugs/surgical items for complete testing as per statutory requirement under D & C Act/ appropriated Pharmacopoeia/Bureau of Indian Standards (BIS)/IS specification and other standards as applicable/ desired for which it is participating in the tender.

(h) Attested copy of approval and GLP Certificate for Drug Testing laboratory, duly renewed up to date issued by the State licensing authority under D & C Rule 1945 and NABL Accreditation certificate duly renewed by the issuing Authority be submitted.

3. Technical bid – Cover -‘A’ including Earnest Money Deposit & other Documents:

The tenderer must submit the following documents in the sealed cover super scribed **Cover -‘A’** (all the documents have to be sealed and copies have to be self attested on all pages).

[a]. The Earnest Money Deposit (EMD) shall be Rs.10,000/-(Rupees Ten Thousand only) paid in the form of **Demand Draft drawn** in favour of **BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA** payable at Delhi/Gurgaon, should be sent with tender form in Cover- ‘A’. The EMD is refundable however it will not earn any interest. EMD in the form of cheque/ cash/ postal order/ e-payment will not be accepted.

The EMD amount of unsuccessful bidder will be refunded to them within 30 days of finalization of tender. In respect of successful bidder (empanelled bidder), the EMD amount will be adjusted towards security deposit.

[b]. Self attested photocopies of Approval/ license issued by State Licensing Authority duly renewed up to date and NABL accreditation certificate.

[c]. Documentary evidence of having analyzed DRUGS/SURGICAL for the last two years with the statement in the performa given at Annexure-I

[d]. Self attested photocopy of certificate of registration for Service Tax should be enclosed in Annexure-II

[e]. Non conviction certificate issued by State Licensing Authority (SLA)/Competent Authority which should not be 6 months old on date of submission of bid.

[f]. Self attested document of the following should be furnished in the format given in Annexure-III

(i). List of qualified personnel employed in Drug Testing laboratory along with their qualification, experience and details of their approvals (copy of the approval).

(ii). List of sophisticated instruments (working condition) available in Drug Testing laboratory.

(iii). Facilities available in Microbiological Section in the laboratory

[g]. A declaration in the Performa given in Annexure-IV duly signed.

[h]. Details of Drugs/Surgical to be analyzed to be given in Annexure-V

[i]. The Declaration for clause 2(e) shall be submitted as per Annexure-VI.

[j]. Documentary evidence regarding constitution of Drug Testing laboratory viz. Memorandum and Articles of Association, partnership deed etc, with details of name, address, telephone no., fax no., e-mail address of Managing Director/ Partner/ Proprietor etc.

[k]. The instruments such as power of attorney, Resolution of Board etc authorizing the tenderer, should be enclosed in the tender (in Cover-‘A’) duly signed by authorized signatory of the Drug Testing laboratory. Such authorized signatory of the tenderer should sign at the bottom of all the pages of the tender documents.

OTHER DOCUMENTS TO BE ENCLOSED: [self attested]

(k). Annual turnover statement which is self attested and certified by the auditors (C.A.) for last two years i.e., 2013-14 and 2014-2015.

(l). Tenderer shall submit the checklist of documents in the enclosed performa in Annexure –VI

4. PRICE BID (COVER-‘B’)

(a). **Price Bid (Annexure VIII)** of the tenderer duly filled in giving the rates for testing, charges for complete testing of each sample and signed on each page by authorized person with company seal, should be sent in separate sealed cover indicating name of the tenderer and superscribing “Price Bid” Cover –‘B’ hereafter called Cover-‘B’.

(b). Cover-‘B’ shall contain the rates quoted by the tenderer only. It shall not contain any other document. No condition shall be indicated in the price bid. All the terms and conditions shall be indicated only in the technical bid.

(c). The tender documents and certificates must be submitted in a separate sealed cover as **Cover-‘A’** and Price Bid shall be kept in separate sealed cover as **Cover-‘B’**. Both **Cover-‘A’** and

Cover-‘B’ shall be kept in single sealed cover on which it shall be superscribed as “TENDER FOR EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF DRUGS/SURGICAL ITEMS FOR 2015-2017

(d). The tender document should reach **General Manager, BPPI, IDPL Corporate Office, IDPL Complex, Dundahera, Gurgaon-122016 (Haryana), till 27/05/2015 upto 15.00 hour.**

(e). If the last date of submission is declared as holiday, the tenders may be submitted on next working day upto 10.30 A.M.

(f). Tenderers should also enclose soft copy of Price Bid in CD along with Cover-‘B’

5. GENERAL CONDITIONS

i. Forms in all annexure should be filled up properly. Every correction should invariably be attested by tenderer, failing which the tender will be summarily rejected.

ii. The tenderer should quote the rates for complete analysis as per the pharmacopoeial or other standards as per provisions of Drugs and Cosmetics Act 1940 for each drug /surgical items and not for individual test to be performed.

iii. The rates should be exclusive of taxes and the rate should be indicated in price bid as per Annexure VIII

iv. The rates quoted and accepted will be binding on the tenderer for stipulated period and on no account any revision will be entertained till the completion of the contract period.

v. If in any circumstances (like breakdown of instrument or non-availability of reference standard and impurities etc.) the Drug Testing Laboratory is unable to test sample of drug /surgical items, the same should be reported within 24 hours from time of breakdown of instrument or non-availability of reference standard of such sample by fax/ e-mail to Manager (Regulatory).

vi. The tender submitted by any laboratory which has been blacklisted/deregistered/ debarred/ banned by the State / Central Govt. organization or its procurement agencies, shall not be considered.

vii. The laboratory will not be permitted to outsource any test from other Drug Testing laboratory and all testing facilities should be available with the lab for which quotation have been given.

viii. The successful lab shall have to make own arrangement for collection of sample from BPPI office, Gurgaon

6. ACCEPTANCE OF TENDER

i. Out of two covers submitted by each tenderer, Cover- ‘A’ will be opened first at **15.30 hours on 27/05/2015** in the presence of tenderers or their authorized representatives who chooses to be

present. After scrutiny of the documents and information furnished in Cover-‘A’ and confirmation of details stated therein, a list of eligible laboratories will be shortlisted.

ii. Cover-‘B’ (Price Bid) of the tenderers found eligible on the basis of scrutiny of Cover-‘A’ will be opened subsequently and the date and time for opening of Cover-‘B’ will be intimated to the shortlisted tenderers. The acceptable rates for analysis will be decided on the basis of L1 rates and will be communicated.

iii. The tenderers other than L1 tenderer will be given opportunity to match L1 rate and after due confirmation, their name/s may also be included in the panel. If required, the empanelled laboratories will be inspected by a team of officials of BPPI as and when need arises.

iv. The tender inviting authority, BPPI reserves the right to accept or reject any tender for any one or more of the items tendered for, without assigning any reason.

v. No tenderer will be allowed to withdraw their bid after opening of Price Bid.

vi. Any Ambiguity in rate, tender shall be rejected.

7. AGREEMENT

All tenderer who are empanelled will have to execute an agreement on non-judicial stamp paper of Rs. 100/-(stamp duty to be paid by tenderer) in favour of BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA within 15 days from the date of intimation received by them from BPPI that their tenders have been accepted. The form of agreement is enclosed in tender document.

8. SECURITY DEPOSIT

The successful tenderers must pay a security deposit of Rs. **20,000/-**(Rupees Twenty Thousand only) including adjustment of EMD amount at the time of execution of agreement referred in Para 7 above by way of DD in favour of BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA payable at Delhi/Gurgaon.

9. COMPLETE ANALYSIS AND REPORTING CONDITION

(a). On empanelment and entrustment of the job, the Drug Testing Laboratory should furnish the test reports within,

(i). 8 days of receipt of sample in case of **non-sterile products**.

(ii). 21 days of receipt of sample in case of **sterile dosage products**.

(iii). Within 24 hours of receipt of sample, the confirmation of its receipt should be given to BPPI by fax / mail.

- (iv). For any delay more than stipulated time as mentioned in para 9 (a)(i) and (ii) as the case may be, 5% of testing charges per week and the part thereof would be deducted as penalty. For consecutively delay for 4 times or more than 8 times in a year or a delay of more than 10 days occurs over the time period stipulated above, then the penalty would be 10% of testing charges per week and part thereof.
- (b). All the test mentioned under IP, BP, USP, BIS, IS and any other standard mentioned as per Second Schedule under D& C Act 1940 and Rules 1945 as well as Schedule V should be carried out for each and every sample. The results obtained in the test should be mentioned in figures. Test reports not mentioning complete details as per IP, BP, and USP, BIS, IS etc will be considered as "Incomplete test report". All the drugs testing laboratory will have to submit complete report for its acceptance failing which appropriate action will be initiated.
- (c). "Complies" or "Passes" or "Within Limit" in result column of the test report will also be treated as incomplete test report. If the result has some value the actual value found on analysis is to be reported in test report to access the intercity of severeness.
- (d). Every test report must have some specific remarks as 'Standard Quality', or 'Not of Standard Quality.' Any ambiguity/ cutting will not be accepted, like sample complies in above test etc.
- (e). Test report should be issued on form 39 and should have name of drug/surgical sample, sample code no., Item Code no, Batch no., Mfg. Date, Exp. Date, Description of tests, Specifications and Results obtained including protocol of test applied/specified. It should be signed by person-in-charge of testing Labs. In case of Not of Standard Quality Reports the final results and reason for failure should be highlighted by red highlighters along with reason.
- (f). Spectra/Chromatograph/Dissolution profile, or other data sheets, wherever applicable, should be attached with the test report.
- (g). In the case of non-pharmacopoeial products the method of analysis should be mentioned in the report AND PROTOCOL OF TEST APPLIED TO BE MENTIONED ON EACH REPORT.
- (h). The test report should be sent to Manager (Regulatory), BPPI office as hard copy and simultaneously scanned copy should be sent by e-mail mquality.janaushadhi@gov.in
- (i). All test report should be submitted to BPPI in duplicate. In case of failure of sample, result should be communicated immediately to Manager (Regulatory), BPPI through phone/ fax/ e-mail and hard copy of test report should be sent with covering letter addressed to Manager (Regulatory) at Bureau of Pharma Public Sector Undertakings of India (BPPI), IDPL Corporate Office, IDPL Complex, Dundahera, Gurgaon-122016 (Haryana) at the earliest possible.
- (j). If in any circumstances (like breakdown of instrument or non-availability of reference standard etc.) the Drug Testing Laboratory is unable to undertake testing of sample, the same should be reported within 24 hours of the receipt of such sample by fax/ e-mail to Manager (Regulatory) and sample should be returned to him immediately. 100% of charges as penalty will be imposed in case no prior information of breakdown of instrument or non-availability of reference standard is given to this office before sending samples. Refer para (5)(v).

(k). If standard test procedure of any product is required the same should be demanded within 48 hours from date of receipt of sample. Period lapsed/taken in providing standard testing procedure will be condoned from prescribed time limit for that sample.

(l). If any sample is received in damaged condition by the laboratory, the sample should not be analyzed and should be sent back immediately to Manager (Regulatory), BPPI and due information should be given by fax/ e-mail.

(m). The Consultant (Quality & Regulatory), Manager (Regulatory), or authorized representatives of BPPI have the right to inspect the laboratories of the tenderer who have submitted tenders before taking any decisions regarding empanelment. They may also inspect the laboratory, which is empanelled at any time during continuance of tender and initiate action to terminate / cancel its empanelment and not to entrust any further testing job to the laboratory if any violation of tender conditions are noticed during such inspections. For gross negligence, the empanelled lab can be blacklisted/debarred/deregistered/banned.

(n). The successful laboratory shall have to make own arrangement for collection of Drug /Surgical samples, from BPPI, Office.

(o). It will be sole discretion of BPPI to allot the samples to any empanelled laboratory in case when there are more than one laboratory approved for an item.

10. PAYMENT PROVISIONS

i. No advance payment towards any analysis will be made to tenderer.

ii. No payment will be made for incomplete analysis or incomplete report. Refer Para 9 (b) to 9 (g)

iii. (a). Payments towards the analysis of DRUGS / SURGICAL items will be made along with tax at the approved rate as applicable at the time of payment strictly as per rules

(b). Bills should be supported with the copy of test report. Efforts will be made to make payments within 30 days from the date of receipt of the bills by BPPI if same are found in order in all respect.

11. PENALTIES PROVISIONS

If the successful tenderer fails to execute the agreement and payment of security deposit after opening of Price Bid within the specified time or withdraws the tender after the intimation of acceptance of tender has been received by them or owing to any other reasons, the tenderer is unable to undertake the contract, the empanelment will be cancelled and security deposit shall stand forfeited to BPPI. Such tenderer will also be liable for all damages sustained by BPPI by reasons of breach of tender conditions. Such damages shall be assessed by CEO, BPPI whose decision shall be final.

12. BLACK LISTING PROCEDURE

(a). Non performance of any tenderer or empanelment conditions will disqualify a laboratory to participate in the next tender.

(b). To assess the correctness of the test results given by the empanelled Drug/surgical testing laboratory, samples would also be taken and sent randomly to Govt. laboratory/ CPSUs Laboratories/ any other NABL accredited labs/ GLP certified Labs which may not be empanelled for testing and if any variation in the results is found, the result would be informed to empanelled laboratory. If there is any major variation in the analytical reports furnished by empanelled laboratories, (either pass or fail etc.) viz-a-viz Govt. /CPSUs Laboratory/ any other NABL accredited labs/ GLP certified Labs, the empanelled laboratory will be blacklisted upto two years besides forfeiture of security deposit, after giving due opportunity to the concerned laboratory.

(c). If it is revealed that Drug Testing Laboratory is involved in any form of fraud and collusion with the suppliers of BPPI, the Drug Testing Laboratory will be black listed upto five years. The tenderer shall also be liable for action under criminal law and matter will also be informed to relevant appropriate authorities for penal action against them.

(d). The CEO, BPPI will be at liberty to terminate the empanelment without assigning any reasons. The tenderer will not be entitled for any compensation whatsoever in respect of such termination.

13. DISPUTE RESOLUTION

Normally, there should not be any scope of dispute between the BPPI and the empanelled laboratory/institution after entering into a mutually agreed valid contract / agreement. However, due to various unforeseen reasons, problems may arise during the progress of the contract / agreement leading to disagreement between the BPPI and empanelled laboratory / institution. However, when a dispute / difference arises, both the BPPI and the empanelled laboratory / institution shall first try to resolve the same amicably by mutual Consultation. If the parties fail to resolve the dispute by such mutual consultation within twenty-one days, then, depending on the position of the case, either the BPPI or the empanelled laboratory/institution shall give notice to the other party of its intention to commence arbitration procedure as per Indian Arbitration and Conciliation Act, 1996. Such disputes/differences shall be referred to Sole Arbitrator to be appointed by the President / CEO of BPPI. The venue of Arbitration shall be at New Delhi. The award published by the Arbitrator shall be final and binding on the parties.

Note:

- In all matters pertaining to tender, the decision of CEO, BPPI shall be final and binding.
- In event of any dispute arising out of tender, such dispute would be subject to the jurisdiction of civil court within Delhi.

- In case of dispute or difference arising between BPPI and empanelled Drug Testing Laboratory relating to any matter arising out of or connected with this tender agreement, such dispute or differences shall be settled in accordance with the Arbitration and Conciliation Act 1996. The venue of arbitration shall be Gurgaon.

14. AGREEMENT FORMAT (Contract for Empanelment of Drugs/Surgical Testing Laboratories for the Analysis of DRUGS/surgical)

Agreement made this _____ day of 2015 at BPPI Gurgaon between M/s _____ having its registered office at _____ (hereafter referred to as 'The Laboratory' which term should include its successors, representatives, hires, executors, and administrators unless excluded by contract) on one part and BPPI having its registered office at New Delhi on other part.

Whereas the Laboratory has agreed to undertake the analytical work of drug/surgical for BPPI, (the list of medicines mentioned in the Schedule attached hereto) at the rates noted therein and in the manner and under the terms and conditions hereinafter mentioned.

And whereas the Laboratory has deposited with the BPPI a sum of Rs 20000/- (Rupees Twenty thousand only) as Security Deposit for the due and faithful performance of this Agreement, to be forfeited in the event of the Laboratory failing duly and faithfully to perform it.

Now these presents witness that for carrying out the said Agreement in this behalf into execution, The Laboratory and the BPPI do hereby mutually convenient, declare, contract and agree each of them with the other of them in the manner following, that is to say,

(1). The term "Agreement", wherever used in this connection, shall mean and include the terms and conditions in tender floated by the BPPI for Empanelment of Drugs Testing, laboratories for the analysis of DRUGS/ Surgical for the two years 2015-2017 the instructions to tenderer, the conditions of tender, acceptance of tender particulars hereinafter defined and those general and special conditions that may be added from time to time.

(2). (a). The Agreement is for undertaking complete analysis of DRUGS / Surgical by the Laboratory to the BPPI of the samples specified in the Schedule attached hereto at the rates noted against each therein on the terms and conditions set forth in the Agreement.

(b). This Agreement shall be deemed to have come into force with effect from _____ and it shall remain in force for a period upto date of _____ and may however be extended for a further period, on mutually agreed terms.

INSPECTION OF LABORATORY:

(3). In respect of the analysis of medicines as specified in the Schedule, the drug testing Laboratory shall allow inspection of the Laboratory at any time during the tender period by a team of Experts/Officials whom the BPPI may depute for the purpose. The Laboratory shall extend all facilities to the team to enable them to inspect premises, testing facilities, technical personals,

reference standards/ working standards/ mandatory documentation and to interact with responsible technical personals under D & C Act 1940 and Rules 1945, in the Laboratory or laboratory.

RECOVERY OF MONEY DUE TO BPPI FROM THE LABORATORY:

(4). All expenses, damages and other money payable to the BPPI by the drug/ Surgical testing Laboratory under any provisions of this Agreement may be recovered from the amount due or subsequently becoming due from the BPPI to the Laboratory under this or any other Agreement. In case such amounts are insufficient to fully cover such expenses, damages or other money payable, it shall be lawful for the BPPI to recover the balance amount from the security deposit of the Laboratory and all other money held by BPPI and in case such Security Deposit is insufficient, then it shall also be lawful for the BPPI to recover the residue of the said expenses, damages and moneys, if necessary, by resorting to legal proceedings against the Laboratory.

AMOUNT OF SECURITY DEPOSIT TO BE MADE BY THE LABORATORY:

(5). The Laboratory shall deposit with the BPPI Rs. 20,000/- as security deposit by way of Demand Draft favoring BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA payable at Delhi/Gurgaon. This agreement comes into effect only after the laboratory has remitted the required amount of security deposit, notwithstanding anything contained in Para 2 (b) of this agreement.

SUBMISSION OF BILLS FOR UNDERTAKING ANALYSIS:

(6).(a). No advance payment towards any analysis will be made to the Laboratory.

(b). All bills/invoices should be raised in duplicate in the name of Manager (Regulatory), BPPI. All payments shall be made by way of cheque drawn in favour of Laboratory account and Crossed Account Payee / NEFT only. The Laboratory shall furnish the details of their bank account no., name of bank and branch, IFSC code no. etc to the BPPI. (An original cancelled cheque leaf issued by their bank should be furnished).

ASSIGNMENT OF CONTRACT PROHIBITED:

(7). The Laboratory shall not, at any time, assign, sub-let or make over the present contract or the benefits thereof or any part thereof, to any person or persons whomsoever.

TERMINATION OF CONTRACT ON BREACH OF CONDITION:

(8).(a). In case the Laboratory fails or neglects or refuses to faithfully perform any of the covenants on his part herein contained or violates the condition in the tender document, it shall be lawful for BPPI to forfeit the amount deposited by the laboratory as security deposit and cancel the contract apart from black listed/debarring/deregistering or banning the laboratory for period of two years.

(b). In case of laboratory fails or refuses to observe, perform, fulfill and keep all or any other or more or any part of anyone of covenants, stipulations and provisions herein contain, it shall be lawful

for BPPI on any such failure, neglect or refusal to put an end to this agreement and there upon every article clause and thing herein contained on the part of BPPI shall cease and be void and in case of any damage, loss, expense, differences in the cost or other moneys than or any time during the continuance of this agreement becoming due or owing by the laboratory to BPPI, it will be opened for BPPI to recover from laboratory all such damages, losses, expenses, differences in cost or other moneys as aforesaid it shall be lawful for BPPI to appropriate the security deposit made by laboratory as herein before mentioned to reimburse all such damages, losses, expenses differences in cost and other moneys as BPPI have sustained, incurred or put to by reason of the laboratory having seen quality of any such failure, negligence or refusal as aforesaid or other breach in the performance of contract.

(c). If at any time during the course of contract it is found that information given by the laboratory to BPPI, either in tender or otherwise, is false, BPPI may put an end to contract / agreement wholly or in part and thereupon the provisions of cause (a) shall apply and initiate suitable /appropriate action as deemed fit.

(9). The BPPI reserves the right to terminate without assigning any reasons therefore the contract/ agreement either wholly or in part without any notice to the laboratory. The laboratory will not be entitled for any compensation whatsoever in respect of such termination of contract by BPPI.

NOTICES ETC., IN WRITING:

(10). All certificates or notices or orders for the time or for extra , varied or altered laboratory, which are to be the subject of extra or varied charges whether so described in the agreement or not, shall be in writing and unless in writing shall not be valid, binding or be or any effect whatsoever.

LABORATORIES NOT TO HAVE ANY INTEREST IN THE OFFICERS CONCERNED AND SUBORDINATED:

(11). The laboratory shall not be in any way interested in or concerned directly or indirectly with any of the officers, subordinates or servants of BPPI in trade, business or transactions nor shall the laboratory give or pay or promise to give or pay any such officer, subordinate or servant directly or indirectly any money or fee or other consideration under designation of custom or otherwise nor shall the laboratory permit any person or persons whomsoever to interfere in the management or performance thereof under power of attorney or otherwise without obtaining the consent of BPPI in writing.

BANKRUPTCY OF THE LABORATORY:

(12). In case the Laboratory at any time during the continuance of the Contract becomes bankrupt or insolvent or commits any act of bankruptcy or insolvency under the provisions of any law in that behalf for the time being in force, or should compound with his creditors, it shall be lawful for the

BPPI to put an end to the Agreement, and thereupon every article, clause and thing herein contained to be operative on the part of the BPPI, shall cease and be void and the BPPI shall have all the rights and remedies given to him under the precedent clauses.

SERVING OF NOTICES TO LABORATORY:

(13). All notices or communications relating to or arising out this agreement or any of the terms thereof shall be considered duly served on or given to the laboratory if delivered to him or left at his premises, place of business as above or through email.

(14). And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any Para herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of CEO, BPPI in the matter shall be final and binding.

(15). In the event of any disputes between the parties the dispute would be subject to the jurisdiction of civil courts within Delhi only.

In witness where the laboratory and CEO, BPPI acting for and on behalf of BPPI have set their hands the day, month and year written above.

Authorized Signatory of BPPI

Name
Address and Seal

Authorized Signatory of Laboratory

Name
Address and Seal

Witnesses for BPPI

Signature
Name
Address

Witnesses for Laboratory

Signature
Name
Address

Proforma for Performance Statement

(1). Name of Laboratory:

(2). Address:

Sr. No.	Surgical Items	No. of samples (complete analysis) tested during		Total no. of Samples
		2012-13	2013-14	
1	Disposable Hypodermic Needles as per BIS			
2	Absorbent Cotton Wool IP.			
3	Hot water Bag as per BS:1970:2012			
4	Surgical Gloves (Sterile) as per IS 13422:1992			
4	Sanitary Napkins as per IS 5405:1980			
6	Diapers			
7	Rolled cotton Bandages			
8.	Crepe Bandage B.P.			
9.	Adhesive Bandages containing Benzalkonium Chloride Solution IP			
10.	Sterile Disposable Syringe with needle as per BIS			
11.	Clinical Thermometer as per IS 3055(part-1)			
12.	Others			

Note: Facilities for LAL test if available

Yes/ NO

M/s

Details of Laboratory and Certificate of Registration for Service Tax

- (1). Name of Laboratory
- (2). Address of Head Office, if any:
- (3). Address of Laboratory
- (4). Name of responsible contact person
- (5). Phone No. :
Mobile No.:
- (6). E-mail :
- (7). Details of Approval/ License issued by Drugs Regulatory Authority*
- (8). Validity of Approval/ License issued by Drugs Regulatory Authority:
- (9). NABL Certificate No. along with discipline*
- (10). Validity of NABL Certificate upto:
- (11). Certificate of Registration for Service Tax: To be enclosed
- (12). Any other certificates with details*

* enclose duly attested copy

M/s

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Personnel in Laboratory

- 1) Total qualified technical personnel engaged in Chemical / Instrumental analysis:
- 2) Total qualified technical personnel engaged in Microbiological analysis:
- 3) Total qualified technical personnel engaged in testing of surgical items:

Details of Competent (Approved) staff by State Licensing Authority

S. No.	Name	Designation	Qualifications	Approval in Chemical / Instrumental/ Microbiological Testing	Experience in relevant analysis (Years)

List of all functional Sophisticated Instruments/ Apparatus including used for testing of Drug & Surgical items

S. No.	Name of Instrument/ Apparatus	Total Number	Make	Date of Installation

Enclose additional paper

M/s

Facilities in Microbiological Section with AHU in Laboratory

- 1) List of reference cultures available (To be given):
- 2) List of reference impurities available (To be given):
- 3) List of reference standard/ working references available (To be Given):
- 4) Details of equipments (e.g. Incubators, Laminar Air Flow etc.)

S. No.	Name of Instrument/ Apparatus	Total Number	Make	Date of Installation

Enclose additional paper

M/s

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Declaration on 100/- non judicial stamp paper (To be attested by Notary)

I / We (Name of Bidder and designation) _____ having our Head Office at _____ and Drug Testing Laboratory situated at (write complete address)_____ do hereby declare that I / we have carefully read all the conditions of the tender of Bureau of Pharma Public Sector Undertakings of India (BPPI), Gurgaon for empanelment of Drugs/ Surgical Testing Laboratories for analysis of DRUGS/ Surgical for two year period (2015-2017) and shall abide by all conditions stated therein.

I/We further declare that we have valid approval/ license issued by Drug Regulatory Authority bearing no. _____ and certificate for compliance of schedule L-1 valid upto _____. Our testing lab is also NABL accreted bearing certificate no. _____ in disciplines _____ which is valid upto _____.

Signature

Name of Authorized Person
Seal of Laboratory

List of Drugs/ Surgical items

S.No.	Item Code	Name of Item with specification	Unit	Quote Yes /No
1	5001	Absorbent Cotton Wool I.P. 75 gm (Non Sterile)	1	
2	5002	Absorbent Cotton Wool I.P. 200gm (Non Sterile)	1	
3	5003	Absorbent Cotton Wool I.P. 500gm (Non Sterile)	1	
4	5004	Crepe Bandage B.P. (15 cmX4 meter)	1	
5	5005	Crepe Bandage B.P. (10 cmX4 meter)	1	
6	5006	Cotton Bandages(Non Sterile) , Size 7.5 cmX4M as per Schedule F-II	1X12	
7	5007	Cotton Bandages(Non Sterile) , Size 10 cmX4M as per Schedule –FII	1X12	
8	5008	Cotton Bandages(Non Sterile) , Size 15 cmX4M as per Schedule F-II	1X12	
9	5009	Adhesive Bandages Washproof 19 mmx72 mm or 19mm X 70 mm containing Benzalkonium Chloride Solution IP eq. to Benzalkonium Chloride 0.5%W/W	1	
10	5010	Sterile Hypodermic Syringe with Needle attached, 24G , Single use-2ml, IS 12050 [Syringe 2 ml with needle 24 G (Sterile, single use, disposable, as per BIS)]	1	
11	5011	Sterile Hypodermic Syringe with Needle attached, 24G , Single use-5ml, IS 12050 [Syringe 5 ml with needle 24G (Sterile, single use, disposable, as per BIS)]	1	
12	5012	Sterile Hypodermic Syringe with Needle attached, 21G , Single use-10ml, [Syringe 10 ml with needle 21G (Sterile, single use, disposable, as per BIS)]	1	
13	5013	Sterile Hypodermic Syringe with Needle attached, 23G , Single use-20ml, [Syringe 20 ml with needle 23G (Sterile, single use, disposable, as per BIS)]	1	
14	5014	Needle 16G (Sterile, single use, disposable, as per BIS)	1	
15	5015	Needle 18G (Sterile, single use, disposable, as per BIS)	1	
16	5016	Needle 23G (Sterile, single use, disposable, as per BIS)	1	

17	5017	Needle 26G X ½" (1.27cm)(Sterile, single use, disposable, as per BIS)	1	
18	5018	Needle 26G X 1½" (3.18) (Sterile, single use, disposable, as per BIS)	1	
19	6001	Surgical Gloves(Sterile) as per IS specifications confirming to IS 13422:1992/ISO Size 16.5 cm (6.5 Inches)	1X50	
20	6002	Surgical Gloves(Sterile) as per IS specifications confirming to IS 13422:1992/ISO Size 17.80 cm (7 Inches)	1X50	
21	6003	Surgical Gloves(Sterile) as per IS specifications confirming to IS 13422:1992/ISO Size 19cm(7.5 Inches)	1X50	
22	7001	Hot water Bag SIZE 25.5cmx17.8cm(10"x7") BS:1970:2012	1	
23	7002	Clinical Thermometer As per IS 3055 (Part-1) Specification, GLASS	1x10	
24	7003	Sanitary Napkins Regular with wings as Per IS Specification No.5405:1980	1	
25	7004	Adult Diapers Medium	1	
26	7005	Adult Diapers Large	1	
27	7006	Adult Diapers Extra Large	1	
28	7007	Baby Diapers Small	1	
29	7008	Baby Diapers Medium	1	

M/s

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Declaration

IManaging Director/Partner/Proprietor of M/s
..... having its registered
office at
do hereby declared that our company have not black listed/ debarred /
deregistered/ either by any state Government or central Government Organization
or its drug procurement agencies. We are eligible to participate in tender
no.....

M/s

Company Seal

To be attested by Notary

CHECK LIST

S. No.	Particulars	Page No.	Yes	No
1.	Annexure VI - Checklist			
2	EMD in the form of DD shall be kept in an envelope.			
3	Self attested and notarized Photo copy of licence for Drug Testing Laboratory renewed upto date.			
4	Accreditation Certificate issued by NABL & its renewal			
5	Annual Turn over for the last two years i.e. 2013-2014 & 2014-2015 certified by the auditors.			
6	<i>GLP compliant under the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 (Schedule L1 certificate.</i>			
7	Certificate for analysis issued by other recognized agencies			
8	Non conviction certificate as per para 3(e)			
9	Annexure – I Proforma for performance statement			
10	Annexure – II Details of Laboratory and Certificate of Registration for service tax			
11	Annexure – III (A) List of technical personnel in laboratory.			
12	Annexure – III (B) List of Sophisticated instruments.			
13	Annexure – III (C) Facilities in microbiological section			
14	1) List of reference cultures available:			
15	2) List of reference impurities available:			
16	3) List of reference standard/ working references available			
17	Annexure – IV Declaration form duly signed.			
18	Annexure – V List of Drugs/Surgical items			
	Annexure – VI Declaration as per para 2(e)			
19	Documentary evidence, for the constitution of the company / laboratory ie., Memorandum and articles of Association or partnership etc.,			
20	The documents such as power of attorney, resolution of board etc.,			
21	The tender document signed by the tenderer on all pages with official seal			
22	Documentary evidence of having analyzed drugs for the test for the last two years			
23	Whether lab engaged in mfg activities (If yes, give details)			
24	<u>Cover B</u> : Annexure – VII (Price Bid) Hard and softcopy in a separate cover			

M/s

Price Bid

S. No.	Item Code	Name of Item with specification	Unit Size	Rate excluding Tax (Rs.)	Tax applicable in %	Total amount including Taxes (Rs.)	Remarks
1							
2							
3							
4							
5							
6							
7							

Enclose Soft Copy of Price Bid (in Excel Sheet) in CD also.

M/s

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