NOT TRANSFERABLE

e- Lab TENDER NO.: - BPPI/Limited/Drug, surgical & food product/04-2019

TENDER FOR EMPANELMENT OF DRUG & SURGICAL TESTING LABORATORIES FOR ANALYSIS OF DRUGS SURGICAL & FOOD PRODUCTS ITEMS FOR THE PERIOD 2019-2020

Dated: 24.12.2019

TO

Bureau of Pharma Public Sector Undertakings of India (BPPI)

BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

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

8th Floor, Videocon Tower, Block E1,
Jhandewalan Extension, New Delhi-110055
Telephone: 011-49431821/4943182349431830;

Website: **janaushadhi.gov.in**

Details of Events are as below: -

Tender Reference			**e-Lab tender no. BPPI/limited/ Drug, surgical & food product /04-2019 Dt. 24/12/2019 (Tuesday)**
Date of availability of tender documents on website			**24/12/2019**
Last date and time for submission of Online Bid i.e. Bid Submission End Date and time			**06/01/2020 up to 3:30 PM (Monday)**
Last Date for submission of EMD in physical Form in office of Bureau of Pharma PSUs of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055			**06/01/2020 up to 5:30 PM (Monday)**
Time and date of opening of Technical Bid			**07/01/2020 (Tuesday) 4:00 PM**
Cost of the Tender Document			**Free of cost**
Address for Communication			**Bureau of Pharma PSUs of India,** **8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055**
Contact Person for clarification if any			**1. Sh. Sunny Tuteja,** **Manager (Quality control)** **Phone: - 011-49431830** **Email: - regulatory@janaushadhi.gov.in**
			2. Ms. Pyrianjali Singh, **Sr. Executive (Quality)** **Phone: - 011-49431823** **Email: - quality2@janaushadhi.gov.in**

			3. Ms. Mahima Bhatnagar, **Sr. Executive (Quality)** **Phone: - 011-49431821** **Email: - quality4@janaushadhi.gov.in**

The tender document can be downloaded free of cost from the CPPP e-Procurement Portal https://eprocure.gov.in and from *the website of BPPI:* ***janaushadhi.gov.in.***

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BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

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

ONLINE TENDER FOR EMPANELMENT OF DRUGS, SURGICAL & FOOD PRODUCTS TESTING LABORATORIES FOR BPPI FOR THE PERIOD (2019-2020) FROM THE DATE OF ACCEPTANCE OF TENDER

"**CONFIDENTIALITY IS THE ESSENCE OF THIS TENDER**"

1. (a) Online tenders are invited by CEO, **Bureau of Pharma Public Sector Undertakings of India (BPPI),** Videocon tower, 8th Floor, E-1, Jhandewalan Extension, New Delhi-110055, **(Herein referred as Tender inviting authority unless the context otherwise requires)** for empanelment of drug testing laboratories (under Drugs & Cosmetics Act 1940 & Rules 1945) having Physical, chemical, instrumental, 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 of one year on mutually agreed terms &conditions. The complete set of tender documents can be downloaded from the BPPI website janaushadhi.gov.in and **CPP portal i.e. eprocure.gov.in** free of cost**.**

2. **(b)** Pradhan Mantri Bhartiya Janaushadhi Pariyojana is the noble project launched by Government of India with the aim of providing quality medicines at affordable price to all through exclusive outlets namely Pradhan Mantri Bhartiya Janaushadhi Kendra. Presently more than 5600 kendras are functional all over India. Product basket contains about 900 generic drugs, 150 surgical consumables and food products. Target is to have about 10000 kendras & a basket of more than 1500 products. The products are purchased from manufacturers through open tender process & are received at our central warehouse at Gurgaon. All batches are got tested from drug testing labs before releasing the product to our kendras through the network of C&F & distributers. Quality checks including testing in the labs are also undertaken during the entire shelf life of the product. During last financial year (2017-18) drugs worth more than 100 crores were procured & more than 5000 samples were drawn for testing. Up to December 2018 (2018-2019), With the opening of 6000 kendras & product basket of more 1500, volume of samples lifted for testing at labs will increased considerably in the coming years.

3. **Tender Inviting Authority** – C.E.O, Bureau of Pharma Public Sector Undertakings of India, 8th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055 (hereinafter referred as **Tender Inviting Authority** unless the context otherwise requires).

4. **Tender Accepting Authority** – CEO, Bureau of Pharma Public Sector Undertakings of India, (hereinafter referred as **BPPI** unless the context otherwise requires).

5. **Tender Inviting Authority** invites **Tender for Empanelment of Drugs, Surgical & food products, Testing Laboratories to BPPI for the Period (2019-2020).**

1. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDERS.

(a)Online Bids [in two separate Cover {Technical bid ("Cover A") and price bid (Cover "B")}] will be uploaded **till 3:30 P.M. up to 06/01/2020 (Monday) on** CPP portal i.e. eprocure.gov.in

(b) The price bid shall be valid for a period of 120 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms &conditions. However, BPPI reserves the right to place purchase orders at the quoted rate till such period.

2. Eligibility Criteria:

(a). Valid National Accreditation Board for Testing and Calibration Laboratories (NABL) and Food safety and standards authority of India FSSAI accredited analytical laboratories.

(b). Lab should have a minimum two years' experience in the analysis of Drugs & surgical items

(c) Lab should have a minimum average annual turnover of Rs. 30 Lakhs for last two financial years i.e. 2017-18 and 2018-19. ***However, turnover for the year* 2017-18 *should not be less than Rs. 30 lakhs.*** Govt./CPSU's Laboratories, Reference Laboratories (having USFDA approval, WHO-prequalified), Research and Development Laboratories, Laboratories run by Co-operative body and Educational Institutions are exempted from the turnover criteria.

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

(e). Drug Testing laboratories should be GLP compliant under the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 and should hold Schedule L1 certificate.

(f). Drug Testing laboratories should not have been banned/debarred/ blacklisted/deregistered by any State or Central Govt. Organizations or its procurement agencies or any national/international agencies.

(g). Drug Testing laboratory and its responsible persons should not have ever been convicted under the D & C Act 1940 and Rules 1945.

(h). Drug Testing laboratory should have all necessary instruments/equipment and required mandatory facilities for testing/analysis including microbiological testing of Drugs and Medicines as per statutory requirements.

3. Technical bid – Cover -'A' (Scan copy of EMD & other Documents to be uploaded):

3.1 The tenderer must upload the following documents in while submitting technical bid hereafter called **Cover - 'A'** (scanned copy of all the documents/pages must be serial numbered, self-attested).

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

Scanned soft copy of the EMD instrument must be uploaded to the e-Procurement portal. and **original EMD instrument should be submitted to BPPI, New Delhi on or before the schedule date of technical bid opening.**

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

[b]. Self-attested Scan copies of Approval/ license issued by State Licensing Authority duly renewed up to date. In case the license is not valid on the date of submission, please upload scan copy of application submitted to licensing authority for renewal of license with the acknowledgement of the licensing authority.

[c]. Self-attested scan copies of NABL accreditation, FSSAI certificate

[d]. Documentary evidence of having analyzed Drugs, Surgical & food products for the last two years with the statement in the Performa given in Annexure-I

[e]. Self-attested Scan copy of certificate of registration for GST should be uploaded in Annexure-II.

(f). Scanned copy Non-Conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted should be uploaded. **The certificate should not be more than 6 months old at the time of submission of technical bid**.

(g). Self-attested document of the following should be furnished in the format given in Annexure-III and then uploaded.

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

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

(iii) Facilities available in Microbiological Section in the laboratory

(iv) Total investment (based on purchase price) made on equipment, apparatus, material required in testing (excluding furniture)

(V) List of accreditations like US FDA, WHO, MHRA, ISO, along with scan copy of certificates

(h). A declaration in the Performa given in Annexure-IV duly signed and notarized.

(i). Details of DRUGS & Surgical to be analyzed are given in Annexure-VA & VB

(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 uploaded 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.

(l). Annual turnover statement certified by the auditors (C.A.) for last two years i.e., 2017-18 and 2018-2019.

(m). Tenderer shall upload the checklist of documents in the uploaded Performa in Annexure –VII at top of technical bid.

(n). Scan copy of USFDA approval/WHO-prequalification/other international agencies if held.

(0) All the documents uploaded should also be signed by the authorized official of the Tenderer.

3.2. The all documents indicated above should be uploaded and shall be opened at the time of Technical bid opening.

3.3 **OPENING OF COVER "A" AND COVER "B" OF TENDER**

a). Only authorized official as declared are entitled to be present at the time of opening of Technical Bid - Cover "A" of the tender submitted by them.

b). In case, the date for opening of technical bid is declared holiday, the technical bid shall be opened on next working day at 11.30 A.M.

c). Tenderers, who are found eligible on satisfying the criteria for technical evaluation/based on undertakings & Declaration, will only be informed the time and date of opening of Price Bid - Cover "B" of the tender.

4. PRICE BID (COVER-'B')

4.1. Cover "B" contains the Price Bid of the Tenderer.

(i) The Tenderer shall fill in the rate (Rs) of complete testing/charges for each sample (not for individual test to be performed), % age rate of GST and total rate inclusive of GST in respective column of BOQ for the items quoted**.**

(a). Cover- 'B' 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.

(b) The rates quoted shall not be varied during the full contract period.

(c) **Testing Price Agreement validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the Lab authority.**

5. GENERAL CONDITIONS

i. The tender document shall be download from the websites janaushadhi.gov.in; and CPP portal i.e. eprocure.gov.in. Tender Document is free of cost. No tender cost is to be deposited.

ii. **Agents are not eligible to participate in the tender.**

iii. 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.

iv. The tenderer should quote the **rates for complete analysis** as per the pharmacopoeia

or other standards as per provisions of Drugs and Cosmetics Act 1940 for each drug or as per manufacturer's procedure (STP/MOA and specifications) wherever applicable and medicine not for individual test to be performed.

v. The rates should be exclusive of GST.

vi. 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.

vii. 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 Medicines, 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 (Quality & Regulatory) regulatory@janaushadhi.gov.in and phone 011-49431830 also.

viii. The tender uploaded by the laboratory which has been banned/debarred blacklisted/deregistered by the State / Central Govt. organization, shall not be considered. (Annexure VI).

ix. The laboratory will not be permitted to outsource any test from other Drug Testing laboratory without the consent of BPPI office.

5.1 **SPECIAL CONDITIONS.**

(i) Bids shall be submitted online only at CPPP website: https://eprocure.gov.in. Manual bids shall not be accepted except for the original documents/instruments as mentioned in tender document.

(ii) Bidders are advised to follow the 'Special Instructions to the Contractors/Bidders for the e-submission of the bids online' available through the link 'Help for Contractors' at the e-Procurement Portal https://eprocure.gov.in.

(iii) Bidder shall not modify the downloaded tender form including downloaded price Bid template in any manner. In case any tender form/Price bid template is found to be tampered with/modified in any manner, such bid will be summarily rejected, Bid Security would be forfeited and bidder is liable to be banned from doing business with BPPI.

(iv)Bidders are advised to check the *website of BPPI: janaushadhi.gov.in* and CPPP website https://eprocure.gov.in at least 3 days prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.

(v) The tender document like EMD, checklist and mandate in single sealed cover on which it shall

be super scribed as "**TENDER FOR EMPANELMENT OF DRUGS TESTING LABORATORIES FOR ANALYSIS OF DRUGS, Surgical & Food products, FOR ONE YEARS (2019-20)** should reach **Manager (Quality and regulatory), BPPI,** Videocon tower, 8th Floor, E-1, Jhandewalan Extension, New Delhi-110055**, till 06.01.2020 UP TO 3:30 PM.**

6. OPENING OF PRICE BID & ACCEPTANCE OF TENDER

6.1 Eligible bidders shall be shortlisted as per following procedure: -

i. The documents and information uploaded in Cover- 'A' will be evaluated by a committee & those found fulfilling eligibility criteria will be shortlisted.

ii. All labs may be audited by an inspection team constituted by BPPI during finalization of tender or tender period. The labs will be shortlisted for opening of the price bid based on report of inspection team. The criteria for shortlisting would be:

a). Number, qualification & experience of technical staff.

b). Number & quality of equipment & material/ reference available in the lab. c). Investment made on equipment & apparatus.

d). Certification by the audit/inspection team that lab is following all the parameters of NABL accreditation.

e) The labs having USFDA approval, WHO prequalified labs, labs approved by other renowned international agencies will be declared technically qualified without audit if such approval is within last 18 months.

6.2 Cover- 'B' (Price Bid) of the tenderers found eligible based on above laid procedure will only be opened (will be intimated after audit to individual lab) in the presence of tenderers or their authorized representatives who chooses to be present. The date and time for opening of Cover- 'B' will be intimated to the selected bidders.

6.3 In determining the lowest evaluated price, the rate quoted per sample inclusive if GST as indicated in respective column of the **BOQ** shall be taken into consideration.

6.4 The tenderers other than L1 tenderer for NABL laboratories will be given opportunity to match L1 rate irrespective of nos. of days quoted to submit test report from the date of sample provided by BPPI and after due confirmation, their name/s will be included in the panel. However, tenderer/tenderers having quoted lesser nos. of days shall be 25% extra rate per day subject to ceiling of maximum 50

% **over L1 rate and such bidder shall be given preference for testing of samples. In case sufficient Laboratories are not empaneled due to any reason, BPPI reserves right to float fresh tender during period of two years.**

6.5 BPPI reserves right to negotiate with L1 bidder in case of required as per CVC guidelines in case L1 was found unreasonable.

6.6 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.

Notes 1.: -In view 25% extra rate per day subject to ceiling of maximum 50% over L1 rate, the bidders are required to offer minimum period in days to submit test report from the date of sample provided by BPPI for testing of drugs quoted by the bidder. The changes in nos. of days quoted by the tenderers in tender to submit test report from the date of sample by BPPI shall not be considered after opening of tender.

7. AGREEMENT

All tenderer who are empaneled will have to execute an agreement on non-judicial stamp paper of Rs. 100/-(stamp duty to be paid by tenderer) in favor 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 available under para13 of tender document.

8. SECURITY DEPOSIT

The successful tenderers must pay a security deposit of Rs. **50,000/-**(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 or Banker Cheque in favor of BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA payable at Delhi/Gurgaon.

9. COMPLETE ANALYSIS AND REPORTING CONDITION

a. (i). On empanelment and entrustment of the job, the Drug Testing Laboratory should furnish the test reports within days as quoted in their price bid, but not more than 8 days of receipt of sample in case of all non-sterile products and not more 21 days of receipt of sample in case of all sterile dosage forms.

(ii). within 24 hours of receipt of sample, the confirmation of receipt should be given to BPPI by fax / mail i.e. quality2@janaushadhi.gov.in, quality4@janaushadhi.gov.in & regulatory@janaushadhi.gov.in

(iii). For any delay more than stipulated time as mentioned in para 9 (a)(i) and (ii), 5% of testing charges per week would be deducted as penalty and gradually increase 5% per week i.e 5% in first week, 10 % second week and 15% third week as so on. For any delay 3 times or more in a quarter year or a delay of more than 7 days over the time stipulated above, then there would be suspension of contract for 3 months. Contract can be revoked on completion of period & undertaking that delay will not happen in future.

(iv). Lab situated in the Delhi/NCR are to collect samples from the warehouse & for outside labs sample will be sent by speed post/courier. The day of collection of samples from warehouse.

(b). All the test mentioned under IP, BP, USP and any other standard mentioned as per Schedule under D& C Act 1940 and Rules 1945 as well as Schedule V and manufacturer's specification should be carried out for each sample. The results obtained in the test should be mentioned in figures. Test reports not mentioning complete details as per IP, BP, and USP etc. will be considered as "Incomplete test report" and the drugs testing laboratory will have to submit complete report for acceptance.

(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.

(d). Every test report must have specific remarks as 'Standard Quality', or 'Not of Standard Quality.' Any ambiguity/ cutting will not be accepted.

(e). Test report should have Sr. No., Description of tests, Specifications and Results obtained including protocol of test applied.

(f). Spectra/Chromatograph/Dissolution profile, or other data sheets, wherever applicable, should be attached with the test report. Calculation sheet should to provide on asking within a day.

(g). In the case of non-pharmacopoeia products, the method of analysis should be mentioned in the report AND PROTOCOL OF TEST APPLIED TO BE MENTIONED ON EACH REPORT. In such cases BPPI will provide STP/MOA after collecting same from manufacturer.

(h). The test report should be sent to Manager (Quality & Regulatory), BPPI office as hard copy and simultaneously scanned copy should be sent by e-mail quality2@janaushadhi.gov.in; quality4@janaushadhi.gov.in and regulatory@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 (Quality & Regulatory), BPPI through phone/ fax/ e-mail and physical report should be sent with covering letter addressed to Manager (Quality & Regulatory) at Bureau of Pharma Public Sector Undertakings of India (BPPI), Videocon tower, 8th Floor, E-1, Jhandewalan Extension, New Delhi-110055.

(j). If in any circumstances (like breakdown of instrument or non-availability of reference standard etc.) the Drug Testing Laboratory is unable to undertake sample, the same should be reported within 24 hours of receipt of such sample by fax/ e-mail to Manager (Quality & 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 before sending samples. Refer para (5)(vii).

(k). 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 (Quality and Regulatory), BPPI and due information should be given by fax/ e-mail.

(l). An authorized representative assigned by this BPPI office have the right to inspect the laboratory who have submitted tenders before taking any decisions regarding empanelment and at any time during the contract period, and initiate action to terminate empanelment and not to

entrust any further testing job to the laboratory if any violation of tender conditions or data or integrity or falsification of data are noticed during such inspections.

(m). Market action, if any, is confirmed on account of testing lapse, 50% of the cost of the market action will be borne by the lab and their services will be immediately terminated Litigation, if any, are need to be in accordance with the law.

NOTE: - The date on which report (complete parameter) is submitted by e – mail will be treated as final day of submission of report.

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

iii.(a). Payments towards the analysis of DRUGS & Surgical will be made along with GST at the prevailing 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). Nonperformance of any empanelment conditions will disqualify a laboratory to participate in the next tender.

(b). As a part of the surveillance, test results given by the empaneled Drug testing laboratory, samples would also be taken and sent randomly to referral lab selected for the purpose by BPPI/ Govt. laboratory/ CPSUs Laboratories/Govt institutions/any other NABL accredited labs which are not empaneled for testing and if any variation in the results is found, the result would be informed to empaneled laboratory. If there is any major variation in the analytical reports furnished by empaneled laboratories, (either pass or fail etc.) viz-a-viz Govt./CPSUs Laboratory/any other NABL accredited labs, the empaneled laboratory will be **blacklisted for two years** besides forfeiture of security deposit, after giving due opportunity to the concerned laboratory.

I. 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 blacklisted for five years.** The tenderer shall also be liable for action under criminal law and matter will 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.

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 empaneled 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 Delhi/Gurgaon.

13. AGREEMENT FORMAT

(Contract for Empanelment of Drugs , Surgical & Food Products Testing Laboratories for the Analysis of Drugs , Surgical & Food Products)

AGREEMENT MADE at _____ this _____ day of_____ 2019 at BPPI

New Delhi 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 FIRST PART and Bureau of Pharma Public Sector Undertakings of India, set up under Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India as a Society registered under the societies registration act XXI of1860, having its Registered Office at Core No. 06, 1st Floor, SCOPE Complex, Lodi Road, New Delhi – 110003, through Mr. _____ S/o _____ , _____hereinafter referred to as **"BPPI"** (which expression shall mean and include its successors and assigns) of the SECOND PART.

WHEREAS the Laboratory has awarded a contract by BPPI to provide report and undertake the analytical work of the BPPI, (the list of medicines mentioned in the Schedule attached hereto Annexure-I and Annexure-II) at the rates noted therein and in the manner and under the terms and conditions hereinafter mentioned.

And whereas the Laboratory has deposited a sum of Rs 50000/- (Rupees Twenty thousand only) as Security Deposit for the due and faithful performance of this Agreement with the BPPI, which shall be forfeited in the event of the Laboratory's failure in performing its duties faithfully.

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, surgicals & food products for the two years 2016-2018 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.

GENERAL TERMS & CONDITIONS:

(2). (a). The Agreement is for undertaking analysis of Drugs, Surgical & Food products by the Laboratory to the BPPI of the samples specified in the Schedule attached hereto Annexure-I and Annexure-II 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 up to date of _____ and may however be extended for a further period of one year, on mutually agreed terms.

(c) Laboratory shall perform services with care, skill, and diligence, in accordance with the applicable professional standards currently recognized by such profession, and shall be responsible for the professional quality, technical accuracy, completeness, coordination, and timeliness of all items and services furnished under this Laboratory Agreement.

(d) Laboratory shall comply with all applicable NATIONAL, state, and local laws, ordinances, codes, and regulations in performing services. If Laboratory fails to meet applicable professional standards, Laboratory shall, without additional compensation, correct or revise any errors or deficiencies in items or services furnished under this Agreement.

(e) Laboratory shall retain, at a minimum, accreditation to ISO/IEC as per rules granted by a national accreditation body. Laboratory shall notify BPPI immediately if accreditation is in jeopardy or lost. Upon BPPI's request, Laboratory shall present BPPI with proof of its accreditation.

(f) For all requests made by BPPI pursuant to this Agreement, time is of the essence. The acceptance of a late performance, with or without objections or reservations by BPPI, shall not waive the right to claim damages for such breach nor constitute a waiver of the requirement of timely performance of any obligations remaining to be performed.

(g) Laboratory shall arrange all facility and every method of analysis/reference/working/impurity standard itself, BPPI have no liabilities to arrange as above. If any laboratory refusing to perform the testing with above unavailability of method of analysis/reference/working/impurity standard after agreement, BPPI shall take the action as per clause 12.0 (a).

(h) Each invoice shall be generated with Ll rate as described on dispatch letter and product, if rate on laboratory invoice exceed with L1 rate, that invoices shall be count cancelled.

(i) All invoice along with original certificate of analysis (COA) shall be received at BPPI office within 15 days after completion of testing, delay above 15 days bill/invoice shall not be entertaining.

(j) In accordance with the Pharmacopoeia official monograph and In house STP, all required tests shall be conducted to completion.

(k) Confidentiality clause: Lab will not share, any information/detail/method which comes to their possession / knowledge during and also even after the expiry of contract, to any other party/customer/BOH without the consent of BPPI.

INSPECTION OF LABORATORY:

(3) In respect of the analysis medicines 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 faculties, technical personals, reference standards/ working standards/ documentation as mandatory under Drug & Cosmetic Act 1940 and Rules 1945, in the Laboratory.

RECOVERY OF MONEY DUE TO BPPI FROM THE LABORATORY:

(4). All expenses, damages and other money payable to the BPPI by the drug 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. 50,000/- 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 BPPI. All payments shall be made by way of cheque drawn in favor 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 listing 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.

I. 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.

(9). The BPPI reserves its 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.

INDEMNIFICATION

(10) Laboratory will hold BPPI harmless and indemnify BPPI for any claim arising:

(1) from Laboratory's noncompliance with applicable governmental laws or regulations,

(2) from injury to Laboratory personnel while performing Laboratory's duties under this Agreement, and

(3) in any manner from the services to be performed under this Agreement and caused by laboratory's acts or negligence.

NOTICES ETC., IN WRITING:

(11). 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:

(12). 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:

(13). In case the Laboratory at any time during the continuance of the Contract becomes bankruptor 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:

(14). 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 or above.

(15). 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 on both parties.

(16) All disputes under this Agreement shall be resolved as follows. Within 15 days after written notification of the dispute, principals or officers of Laboratory and BPPI shall meet in an effort to resolve the dispute. If the dispute remains unresolved, the parties shall participate in a facilitated mediation pursuant to the rules of the Indian Arbitration and Conciliation Act, 1996, Such disputes/differences shall be referred to Sole Arbitrator to be appointed by the President/ CEO of BPPI in accordance with the provisions of Arbitration Act, 1996.

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

(18) If any of the provisions of this agreement are held to be invalid or unenforceable in any respect, the remaining terms will remain effective and the agreement will be construed as if the invalid or unenforceable matters were never included in it. No waiver of any default will be a waiver of any future default. Neither party shall be liable for nonperformance caused in whole or in part by Acts of God, civil unrest and war.

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 Signature of BPPI	**Authorized Signature of Laboratory**
Name	Name & designation
Address and Seal	Address and Seal

Witnesses for BPPI	**Witnesses for Laboratory**
Signature	Signature
Name	Name
Address	Address

ANNEXURE-I

Proforma for Performance Statement

1 Name of Laboratory:

2 Address:

Performance

3 Statement:

Sr. No.	Category	No. Of samples (complete analysis) tested during)						Total no. of Samples	Number of samples declared sub standard (NOSQ)
		2017-18			2018-19				2018-19
1	Tablets								
2	Capsules								
3	LVP / SVP								
4	Dry Powder Injectable (DPI)								
5	Liquid Orals/Syrups /Susp.								
6	Ointments/ Creams/Gel/								

	Lotion								
7	Eye/Ear Drops / Nasal Drops								
8	Vaccines & Sera								
9	Biologicals								
10	Surgical								
11	Non drugs								
12	Food supplements								

Note: Facilities for LAL test if available – Yes/NO

ANNEXURE-II

Details of Laboratory and Certificate of Registration for GST

(1). Name of Laboratory

(2). Address of Head Office, if any:

(3). Address of Laboratory

(4). Name of 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:

(11). Certificate of Registration for Service Tax: To be uploaded

12). Any other certificates with details*

* upload duly attested scan copy

ANNEXURE-III-A

Personnel in Laboratory

1) Total qualified technical personnel engaged in Chemical / Instrumental analysis:

2) Total qualified technical personnel engaged in Microbiological analysis:

3) 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)

ANNEXURE-III-B

List of all functional Instruments/ Apparatus used for testing

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

Enclose and upload additional paper

ANNEXURE-III-C

Facilities in Microbiological Section with AHU in Laboratory

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

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

Enclose and upload additional paper

ANNEXURE-IV

Declaration Form (To be attested by Notary)

I / We _ (Name of Bidder) _____ having our Head Office at

_____ And Drug Testing Laboratory at _____ 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), New Delhi for empanelment of Drugs Testing Laboratories for analysis of DRUGS,,Surgicals and food products for two-year period (**2019-2021**) and abide by all conditions said therein.

I/We further declare that we have valid approval/ license issued by Drug Regulatory Authority bearing no. _____ And NABL Certificate bearing no. _____ in discipline _____.

Signature

Name of Authorized Person

Seal of Laboratory

Annexure – V

List of Drugs, Surgical and food products for the Analysis and testing for THE YEAR 2019-2020

S.N	Drug code	Product Name	Unit size	Maximum days require for testing	Sample quantity
1	372	METFORMIN HYDROCHLORIDE TABLETS IP PROLONG RELEASE 500 MG	10's	8	5 strips
2	385	CEFIXIME 200 mg + CLAVULANIC ACID 125 mg (AS POT.CLAVULANATE)Tablets	10's	8	5 strips
3	395	CEFUROXIME 500 mg+ CLAVULANIC ACID 125 mg (AS POT.CLAVULANATE) Tablets	6's	8	9 strips
4	417	TELMISARTAN IP 40 mg+ AMLODIPINE 5 mg Tablets	15's	8	4 strips
5	418	ROSUVASTATIN Tablets IP 20 mg	15's	8	4 strips
6	420	ATORVASTATIN 10 MG+ CLOPIDOGREL 75 MG CAPSULES	10's	8	5 strips
7	429	ATORVASTATIN 10 mg+ FENOFIBRATES 160 mg Tablets IP	15's	8	4 strips
8	465	DOMPERIDONE 30 mg+ PANTOPRAZOLE 40 mg Capsules [SR]	10's	8	5 strips
9	476	LIQUID PARAFFIN 1.25 ML+ MILK OF MAGNESIA 3.75ML+ SODIUM PICOSULPHATE 3.33MG /5ML SUSPENSION 170ml	170 ml Bottle	8	3 bottles
10	498	FERROUS ASCORBATE 100MG WITH FOLIC ACID 1.5MG TABLETS	10's	8	5 strips
11	508	LEVETIRACETAM Tablets 500 mg	10's	8	5 strips
12	511	PARACETAMOL Tablets IP 650 mg	15's	8	4 strips
13	525	DICLOFENAC 1.16 w/w+ LINCEED OIL3% w/w+ METHYL SALICYLATE 10% w/w+ MENTHOL 5% w/w GEL	30 GM	8	12 tube
14	531	GUAIFENESIN 100 mg+ TERBUTALINE 2.5 mg+ BROMHEXINE 8 mg /10 ml SYRUP	100 ml	8	3 bottles
15	580	Ginseng, Multivitamin and Multiminerals Capsules	10's	8	5 strips
16	589	CALCIUM 500 mg+ CALCITRIOL 0.25mcg Tablets 15's	15's	8	4 strips
17	592	L-LYSINE + MULTIVITAMINS (VIT-B1,B2,B3,B5,B6) SYRUP	200 ML	8	3 bottles
18	611	Cyproheptadine, Hydrochloride(anhydrous) IP..2 mg.In a flavoured syrup base ….q.s.	200 ml	8	3 bottles
19	626	Ketoconazole Shampoo 2% W/V	100ml Bottle	8	3 bottles
20	634	Clobetasol Proppionate BP0.05%w/wNeomycin IP0.50%w/wMiconazole IP2%w/wChlorocresol IP0.10 %w/wCream	20 gms.	8	12 tube

21	639	Terbutaline Sulphate 1.25 mg, Bromhexine 4 mg, Guaiphenesin 50 mg Menthol 2.5 mg/5ML Syrup	100 ML	8	3 bottles
22	648	Diclofenac dethylamine BP1.16%Linseed Oil BP3% w/wMethylsalicylate IP10%w/wMenthol IP5% w/wSpray	35gm	8	12 tubes
23	655	Enyme Syrup Mix Fruit Flavour Pepsin 7.5 mg + Fungal Diastase 12.5 mg / 5 ml	200 ml	8	3 bottles
24	658	Chlorhexidine Gluconate 0.3%v/v+Cetrimide 0.6%w/v Antiseptic Liquid 100 ML	100 ML	8	3 bottles
25	659	Chlorhexidine Gluconate 0.3% v/v + Cetrimide 0.6%w/v	200 ml	8	3 bottles
26	670	Diacerein 50 mg + Methyl Sulphonylmethane 250 mg + Glucosamine Sulphate 750 mg Tablets	10's	8	5 strips
27	682	Rabeprazole 20mg + Domperidone 10mg Capsule	10's	8	5 strips
28	713	Glibenclamide 5mg + MetforminHcl 500 mg Tablet	10's	8	5 strips
29	720	Ringer Lactate 500ml IV fluid in FFS technology plastic container	500ml in FFS bottle	21	8 bottles
30	752	Clotrimazole 1% 100 gm powder	100 gm Powder	8	2 bottles
31	767	Metformin 1000mg Prolonged Release + Glimipride 2mg Tablet IP	10's	8	5 strips
32	790	Aspirin enteric coated Tablets I.P. 75mg	14's	8	4 strips
33	904	Glimepiride 1mg Metformin SR 500mg Tablets	10's	8	5 strips
34	1059	Sodium Valproate EC Tablets I.P 200mg	10's	8	5 strips
35	1060	Sodium Valproate Tablets 300mg	10's	8	5 strips
36	1099	Voglibose 0.3 mg, Metformin 500mg Tablets	10's	8	5 strips
37	1129	Teneligliptin 20mg + Metformin 500mg Tablet Sustained Release	10's	8	5 strips
38	1130	Teneligliptin 20mg + Metformin 1000mg Tablet SR	10's	8	5 strips
39	1240	GLICLAZIDE 80 mg + METFORMIN HYDROCHLORIDE Tablets 500 mg 10's	10's	8	5 strips
40	1442	GLUCOSE POWDER 300g (ORANGE FLAVOUR)	300g Box	8	2 boxs
41	1284	Cilnidipine 10mg + Telmisartan Tablet 40 mg	10's	8	5 strips
42	1367	Olmesartan + Amlodipine + Hydroclorthiazide Tablet 20/5/12.5 mg	10's	8	5 strips
43	1392	Rosuvastatin 10mg + Aspirin Capsule 75mg	10's	8	5 strips
44	1437	Cefpodoxime Proxetil 50mg Oral Suspension	30 ml	8	5 bottles
45	1438	Voglibose+Metformin+Glimepiride Tablet SR 0.2/500/2 mg	10's	8	5 strips
46	1445	Jan Pudina Soft Gel Capsules (Pudina ka satva(Mentha Sylvestria)=180mg, Ajwain oil(Trachyspermum Ammi)=20mg, Anethi Oil (Anthum Graveolens)=5mg, Tulsi Oil	10's	8	10 strips
47	1446	Stevia Natural Sweetener (Madhurak)	1's	8	2 bottles
48	1297	Domperidone + Ranitidine Tablet 10/150 mg	15's	8	4 strips
49	1386	Ramipril + Hydroclorthiazide Tablet 5/12.5 mg	10's	8	5 strips

50	1393	Rosuvastatin 10mg + Clopidogrel 75mg Capsule	10's	8	5 strips
51	1447	Jan Aushadhi Janani (Nutrient supplement for women)	1's	10	2 containers
52	1459	Jan Aushadhi Poshan (Food supplement)	1's	10	2 containers

Annexure – VI

Ref. Clause no. 2 (f), 5. viii

Declaration

I ……Managing Director/Partner/Proprietor of M/s

…….. having its registered office at …… ……

do hereby declared that our company have not been banned/black listed/ debarred / deregistered/ either by any state Government or central Government Organization or its drug procurement agencies or any national or international agency. We are eligible to participate in tender no……

M/s …….

Company Seal

To be attested by Notary

CHECK LIST

S.N	Particulars	Page No.	Yes	No
1	Annexure VI - Checklist			
2	EMD Rs 10000 in the form of DD no_____ dated _____issued by _____shall be uploaded and delivered to BPPI.			
3	Self-attested and notarized scan copy of license for drug/surgical/food products testing laboratory renewed up to date.			
4	Recognition Certificate issued by NABL & FSSAI, and its renewal			
5	Annual Turnover for the last two years certified by the auditors. i.e. 2016-2017 & 2017-2018 certified by the auditors.			
6	*GLP compliant under the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 (Schedule L1 certificate.*			
7	Non-conviction certificate as per para 3(f)			
8	Annexure – I Performa for performance statement			
9	Annexure – II Details of Laboratory and Certificate of Registration for service tax			
10	Annexure – III (A) Personnel in Laboratory.			
11	Annexure – III (B) List of Sophisticated instruments.			
12	Annexure – III (C) Facilities in Microbiological section 1)List of reference cultures available: 2)List of reference impurities available: 3) List of reference standard/ working references available			
13	Annexure – IV Declaration form duly signed & notarized.			
14	Annexure – VI Declaration as para 2(f) 5. viii			
15	Documentary evidence, for the constitution of the company / laboratory i.e., Memorandum and articles of Association or partnership etc.,			
16	The instruments such as power of attorney, resolution of board etc.,			
17	The tender document signed by the tenderer in all pages with official seal			
18	Documentary evidence of having analyzed drugs for the test for the last two years			