PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)
(Set up under the Department of Pharmaceuticals, Govt. of India)
8th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Amendment No. 2

Ref. No: - PMBI/Empanelment/Drug Testing Laboratory/09-2023 **Dated: 04.09.2023**

Tender No. PMBI/Empanelment/Drug Testing Laboratory/09-2023 dated 10/08/2023 for Empanelment of Testing Laboratories for Analysis of Drugs, Surgical/Consumables/Medical Devices, Ayurvedic & Food Products for the period of 2023-2025 to Pharmaceuticals and Medical Devices Bureau of India (PMBI).

Ref: 1. Queries of Pre-Bid meeting held on 18.08.2023 at 11:00 hrs. in conference hall of PMBI (9th Floor)
2. Bidder's query received through E-mail.

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for "e- Tender for Empanelment of Testing Laboratories for Analysis of Drugs, Surgical/Consumables/Medical Devices, Ayurvedic & Food Products for the period of 2023-2025", vide Notice Inviting e-Tender No.- PMBI/Empanelment/Drug Testing Laboratory/09-2023 dated 10/08/2023. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; www.eprocure.gov.in and PMBI Website; www.janaushadhi.gov.in.

The following amendment in Tender Document is hereby authorized as:

S. No.	Tender Clause / Reference	Query / Suggestion	Clarification / Amendment
1.	**3. ELIGIBILITY CRITERIA (TECHNICAL BID -COVER "A"): F(b)**	Bidder has raised query in reference to the eligibility criteria under clause no. 3 F(b), that, batch details of the quoted product tested by them under 21CFR Compliance for last 2 years is very bulky process so it can't be uploaded on CPP Portal so bidders have requested to upload the summary on CPP Portal and complete batch details provided in Link on mail already mentioned in tender and in hardcopy & all the data verified at the time of Audit/Inspection.	In this regard, it is clarified that bidders upload the Summary of batch details of the quoted product tested under 21 CFR Compliance for last 2 years on CPP Portal & complete batch details provided in link on mail already mentioned in tender and in hardcopy & all the data will be verified at the time of Audit/Inspection.

2.	**(TECHNICAL BID - COVER "A"): CLAUSE 13.1.1. IN POINT NO.4**	Bidder has raised query in reference under-clause no. 13.1.1 in point no-4, that remove mandatory staff conditions from tender conditions as in private sector every year approx. 30% of employees left the organization and new employees joined the organization.	Tender condition prevails.
3.	**(TECHNICAL BID - COVER "A"): CLAUSE 13.1.1. IN POINT NO.5**	One of the intending bidders has raised query in reference to point 5 of clause no. 13.1.1 that Gas Chromatography with Flame Ionized Detector (GC with FID detector) & GC with Head space are same.	ln this regard, it is clarified that Both instruments are same, so 2(two) marks will be considered in scoring system in clause 13.1.1. in point 5.
4.	**(TECHNICAL BID - COVER "A"): CLAUSE 13.1.1. IN POINT NO.6**	Bidder has raised query in reference under-clause no. 13.1.1. in point 6, that qualification data of Instruments (Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) submission is very bulky process so it can't be uploaded on CPP Portal so bidders have requested to upload the summary of qualification data of Instruments on CPP Portal & complete Qualification data of Instruments provided in link on mail already mentioned in tender and in hardcopy & all the qualification data of Instruments verified at the time of Audit/Inspection.	ln this regard, it is clarified that bidders uploaded the summary of qualification data of Instruments (Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) on CPP Portal & complete Qualification data of Instruments provided in link on mail already mentioned in tender and in hardcopy & all the qualification data of Instruments verified at the time of Audit/Inspection.
5.	**ANNEXURE-IX CLAUSE 4.P and 19 B(iii) Evaluation Test Parameter for various Dosage form**	Bidder has raised query in reference to annexure no-IX that addition of metered dose in inhaler dosage form & preservative test if applicable & Addition of Ethylene Glycol (EG) and Diethylene Glycol (DEG) test in syrup.	After due deliberation, the committee has agreed to amend in Annexure IX of the clause 4.P and 19 B(iii) Addition of metered dose in inhaler dosage form & preservative test if applicable & Addition of Ethylene Glycol (EG) and Diethylene glycol (DEG) test in syrup.
6.	**3. ELIGIBILITY CRITERIA (TECHNICAL BID -COVER "A"): A**	Bidder has raised query in reference to the eligibility criteria under clause no.3 if a laboratory has an MSME / Udyam Registration Certificate with Service Industry (74909 - Other professional, scientific and technical activities n.e.c). may be exempted for submission	Tender condition prevails.

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<tr><td></td><td></td><td>of EMD.</td><td></td></tr>
<tr><td>7.</td><td>3. ELIGIBILITY CRITERIA (TECHNICAL BID -COVER “A”): H(a) & 13.1.1. in Point 4</td><td>Bidder has raised query in reference to the eligibility criteria under clause no. 3 H (a) & clause 13.1.1 in point no.4, If one lab has 2 or more person-in- charges who are approved in Chemical, Instrument & Microbiological analyst shall be deemed as Approved microbiologist or not if 1 approved microbiologist is not available.</td><td>ln this regard, it is clarified that if one lab has 2 or more person-in charge who are approved in chemical, instrumental, Microbiological Analyst then they are also deemed as Approved Microbiologist.</td></tr>
<tr><td>8.</td><td>(TECHNICAL BID - COVER “A”): CLAUSE 13.1.1. IN POINT NO.5</td><td>Bidder has raised query in reference to the eligibility criteria under clause no. 13.1.1 in point no.5 If one lab has total 4 HPLC (All 4 are with UV Detector and out of which one with Both UV Detector and RI detector) shall be sufficient to qualify.</td><td>ln this regard, it is clarified that if one lab has total 4 HPLC (All 4 are with UV Detector and out of which one with Both UV Detector and RI detector) will be considered to qualify.</td></tr>
<tr><td>9.</td><td>ANNEXURE-X
List of Drugs, Surgical/Consumables /Medical Devices, Ayurvedic & food products for the Analysis and testing for the year 2023-2025.</td><td>Bidder has raised query in reference to Annexure-X, DC-2068 & DC-2069 that content of the kit and their generic specification is not mentioned.</td><td>The amendment is hereby authorized as follow:
<table>
<tr><th>S. No.</th><th>Product name</th><th>Drug code</th><th>Unit Size</th><th>Maximum days require for testing</th><th>Sample quantity</th></tr>
<tr><td>1299</td><td>Ayuraksha Immuno Boosting Kit (Chawanprash 180g-1unit, Ayush Kwatha 100g-1unit, Samsamani Vati 120 Tablets -1unit, Anu Taila 10ml-2units)</td><td>2068</td><td>Kit</td><td>8</td><td>7</td></tr>
<tr><td>1300</td><td>Bal Raksha Kit (Chawanprash Avaleha 180g-1unit, Syrup Ayush Bal Kwatha 100ml-3units, Samsamani Vati 120 Tablets -1unit, Anu Taila 10ml-2units)</td><td>2069</td><td>Kit</td><td>8</td><td>7</td></tr>
</table></td></tr>
<tr><td>10.</td><td>ANNEXURE-X
List of Drugs, Surgical/Consumables /Medical Devices, Ayurvedic & food products for the Analysis and testing for the year 2023-2025.</td><td>One of the intending bidders has raised query in reference to Annexure-X, that in DC-600 & DC-1839, Dosage form and maximum days required for testing is not mentioned.</td><td>The amendment is hereby authorized as follow:
<table>
<tr><th>S. No.</th><th>Product name</th><th>Drug code</th><th>Unit Size</th><th>Maximum days require for testing</th><th>Sample quantity</th></tr>
<tr><td>457</td><td>Paracetamol IP 170 mg, Phenylephrine Hydrochloride IP 2.5 mg, Dextromethorphan Hydrochloride IP 5 mg syrup</td><td>600</td><td>60 ml</td><td>10</td><td>8</td></tr>
<tr><td>1130</td><td>Vitamin B complex with vitamin B12 Injection</td><td>1839</td><td>2ml</td><td>21</td><td>30</td></tr>
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11.	**(TECHNICAL BID - COVER "A"): CLAUSE 13.1.1. IN POINT NO.6**	Bidder has requested to amend 2 years under clause 13.1.1 point .6 (Declaration on Non-Judicial Stamp Paper Duly Notarized forNSQ batch) with 3 years in reference to clause no. 3 L	After due deliberation, the committee has agreed to amend the part of the clause 13.1.1. in point 6 in reference to clause 3L. i.e., **For:** Declaration on Non-Judicial Stamp Paper Duly Notarized for NSQ batch by lab for last 2 years in prescribed format as per Annexure-V. **Read as:** Declaration on Non-Judicial Stamp Paper Duly Notarized for NSQ batch by lab for last 3 years in prescribed format as per Annexure-V.
12.	**ANNEXURE-IX CLAUSE 4.P and 19 B(iii) Evaluation Test Parameter for various Dosage form**	Bidder has raised query in reference to annexure no-IX that NDMA impurity is added in Ranitidine tablets.	After due deliberation, the committee has agreed to amend the Annexure-IX with reference to clause 4P & 19B(iii), Addition of NDMA impurity in Ranitidine tablets.

All other contents of tender document remain unaltered. Bidders are requested to quote their Items for Testing considering all the terms and conditions of the tender document including Amendment no. 1 dated 25/08/2023 and this Amendment no. 2 dated 04/09/2023.

Sd/-
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