

PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

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

8th& 9th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Amendment no. 2

No.: -PMBI/AYURVEDIC/RC-205/2022

DATED: 06/10/2022

Subject: - Tender No. PMBI/AYURVEDIC/RC-205/2022 dated 06/10/2022 for supply of Ayurvedic Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI) for two years under rate contract.

Reference: - i. All queries of Pre-Bid meeting held on 21/10/2022 at 15:00 Hours in the premises of PMBI.
ii. Bidders query received through mails.

1. Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for “e- Tender for Supply of Ayurvedic Drugs for the year 2022-2024”, vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-205/2022. 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.
2. After considering the suggestions/ queries received from the prospective bidders, the clarifications/ amendments regarding the specification, packing and dates in tender document have been made as per Part-A & Part-B. All other technical specifications, terms, and conditions along with the tender schedule as mentioned in tender document shall remain unchanged.
3. The following amendment in Tender Document is hereby authorized:

Part-A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Clarification/ Amendment
1	Clause no. 3. D (a). Eligibility criteria (Technical bid -cover “A”) at page 9 of the tender document.	The bidder stated that the instant tender is an Ayurvedic Drugs tender and Sudh Madhu (Honey) of various pack size (DC-2377, DC-2378 & DC 2379) has been invited under food category with FSSAI License which may create confusion and lack of awareness among prospective bidders of food category products.	Clause No. 3.D (a) is amended as: <u>Minimum three years old valid Manufacturing License of the quoted product on Form no. 25D.</u>
2	Clause no. 3. D (e). Eligibility criteria (Technical bid -cover “A”) at page 9 of the tender document.	One of the bidders stated that they have ceased production for some items due to uncertain demand from the market during COVID pandemic. Hence, they could not fulfil the “Market Standing Certificate” for latest three years although they have manufacturing license for latest three years. Therefore, requested to amend the latest 3 years market standing certificate.	Tender condition prevails.
3	Clause no. 3. G. Eligibility criteria (Technical bid -cover “A”) at page 9 of the tender document.	The bidder requested to relax the WHO GMP certificate as eligibility criteria and to accept the ayurvedic products with Ayush Premium mark.	Tender condition prevails.

4	Clause no. 3. H. Eligibility criteria (Technical bid -cover "A") at page 9 of the tender document.	One of the bidders stated that the "Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department" is not issued by licensing Authority. The CA certified/Self attested production certificate may be accepted	Clause No. 3.H is amended as: Maximum Production Capacity Certificate (section wise) issued by <u>Licensing Authority from Drugs Control Department or CA and countersigned by Company Secretary / Authorized signatory, highlighting the quoted product section. The maximum production capacity should be commensurate with the WHO-GMP inspection report.</u> Self-attested copies are to be submitted. Accordingly, the item under Sl. No.11 in the Checklist of Annexure-I is also amended.
5	Clause no. 3. I. Eligibility criteria (Technical bid -cover "A") at page 10 of the tender document.	Few bidders have requested to lower the required annual average turnover for any three of the last four consecutive financial than 10 Crores (Ten crore) as mentioned in the tender.	Tender condition prevails.
6	Clause no. 3. R. Eligibility criteria (Technical bid -cover "A") at page 10 of the tender document.	One bidder wanted clarification regarding the Copy of valid GS-1 registration certificate from GS1 India as mandatory requirement because their products have already barcode in them.	Tender condition prevails.
7	Clause no. 4. P. (ii). General Conditions at page 13 of the tender document.	The bidders have stated that the sample receipt format have not been mentioned in the tender.	Annexure XVI- Sample Receipt Format required as mentioned at Clause No. 4. P (ii) is placed at Part- C
8	Clause no. 4. P. (iii). General Conditions at page 13 of the tender document.	The bidder had enquired regarding the samples which has to be submitted in the tender should be as per their own marketed product or as per the packing specifications mentioned in the tender. The bidders further asked that the samples are required to submit in along with test report or not?	Clause No. 4.P (iii) is amended as: <u>Sample has to be submitted in pack as specified in the tender or as own available market/ trade pack duly labeled,</u> otherwise the quotation against that particular item is liable to be rejected. However, the bidder has to comply with the packaging specifications as mentioned in the tender while supply. The bidder has to submit in house/NABL test report along with sample complying with the specifications mentioned at Annexure- XII.
9	Annexure-I Checklist (Whether uploaded the documents) at Page No. 32 of the tender document.	One of the bidders has pointed out that the required annual turnover has been mentioned as 25 crores at Sl. No. 13 of Checklist in the Annexure-I	The Checklist Sl. No 13 of Annexure-I is hereby amended as: Copy of Audited Annual Balance sheet and Profit and loss statement showing details of their annual turnover not less than <u>10 crores</u> for any three of the last four consecutive financial years as per Clause 3. I.

Part - B: -

I: The following Amendment in Specification is hereby authorized: -

Sl. No.	Tender Clause/ Reference	Sl. No. in the tender document	Drug Code	Generic Name of the Drug	Detailed Specification	Unit Size	Bidders Query	Amendment
1	Annexure - XII Clause 18 (M)	1	DC-2374	Shilajit Capsule 500 mg	Each Capsule Contains: Shudhha Shilajit (Asphaltum Punjabianum) 500 mg (exudate)	60's in Bottle	The bidder requested to amend the strength to 300 mg	No Change. Tender condition prevails.
2	Annexure - XII Clause 18 (M)	2	DC-2375	Triphala Tablets 500 mg	Each 500mg Tablet Contains: Amlaki Fruit (Emblica officinalis) 168 mg Bibhitaki Fruit (Terminalia Bellerica) 166 mg Haritaki Fruit (Terminalia Chebula) 166 mg	60's in Bottle	The bidders stated that the strength of all three active ingredients should have equal weight	Technical specification of the product is Amended as : <u>Each Tablet should Contain Amlaki Fruit (Emblica officinalis), Bibhitaki Fruit (Terminalia Bellerica) & Haritaki Fruit (Terminalia Chebula) - 500 mg in equal proportions.</u>
3	Annexure - XII Clause 18 (M)	3	DC-2376	Ashwagandha Tablets 250 mg	Each 250mg Tablet Contains: Ashwagandha (Withania Somnifera) 250 mg (Root extract)	60's in Bottle	The bidder requested to amend the dosage form to Tablets against capsules	No Change. Tender condition prevails.
4	Annexure - XII Clause 18 (M)	4	DC-2377	Madhu (Makshik) 100 g	Shudh Madhu (Shahad) Type: Makshik (The composition of the Product 'Shudh Madhu' shall conform the "Bhava Prakash Nighantu". C4 Sugar % by mass: Not more than 7% Moisture not less than 20% by mass Confirms to the standard laid down by FSSAI and IS 4941:1994	100 g glass bottle	The bidders wanted to clarify that the Item Shudh Madhu (Honey) be accepted with FSSAI license only.	Technical specification of the product is Amended as : Shudh Madhu (Shahad) <u>The composition of the Product 'Shudh Madhu' shall conform to the standards laid in Ayurvedic Pharmacopoeia of India.</u>
5	Annexure - XII Clause 18 (M)	5	DC-2378	Madhu (Makshik) 250 g		100 g glass bottle		
6	Annexure - XII Clause 18 (M)	6	DC-2379	Madhu (Makshik) 500 g		100 g glass bottle		

7	Annexure - XII Clause 18 (M)	7	DC-2380	Chyawanprash Special 500g Jar	The composition of the product 'Chyawanprash Special' shall conform the "Ayurveda Saar Sangrah (A.S.S.)" The taste of the Chyawanprash Special shall be developed as per PMBI's acceptance/requirement. Unrefined cane sugar/jaggery should be used for sweetness	500 g Jar	The bidder requested the composition of Chyawanprash Special as per A.S.S. and requested to remove jiggery from the composition.	Technical specification of the product is Amended as : <u>The composition of the product 'Chyawanprash Special' shall conform the "Ayurveda Saar Sangrah (A.S.S.)" The taste of the Chyawanprash Special shall be developed as per PMBI's acceptance/requirement.</u>
8	Annexure - XII Clause 18 (M)	8	DC-2381	Chyawanprash Special 500g Jar		1 Kg Jar		

Part - C: -

I: The following Amendment in Specification is hereby authorized: -

**ANNEXURE- XVI
[Ref. Clause No. 4. P (ii)]
SAMPLE RECEIPT**

(To be submitted in triplicate on firm's letterhead along with samples)

TENDER NO.....

Dated.....

Please receive following Samples of Ayurvedic Drugs from.

M/s.....

.....

S.N	Item No.	Product Name	Batch no.	Date of Manufacturing	Date of Expiry	License No	Number of units submitted

Total number of Items submitted:

Total number of Boxes submitted:

Total Number of signed pages of Pilot studies / Publications: ...

Place:

Date:

Signed.....

Name:

Designation.....

(Company Seal)

(Above shall be furnished by Authorized Signatory)

- 4. All other contents of tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and condition of the tender document including Amendment no. 1 dated 21/10/2022& Amendment no. 2 dated 09/11/2022. Bidders are also requested to refer MoM of the pre-bid meeting for clarification.**

Sd/-
DGM (Procurement& Quality)
For & on behalf of PMBI
PH: 011-49431811