

## PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Under the Department of Pharmaceuticals, Govt. of India)

B-500, B-Tower, 5th Floor, Nauroji Nagar, World Trade Center, New Delhi-110029

### Amendment No. 2

No: PMBI/DRUG/RC-218/2024.

Dated: 29/11/2024

**Subject: - e-Tender No. PMBI/DRUG/RC-218/2024 dated 05/11/2024 for Supply of Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI).**

Pharmaceuticals & Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested eligible parties for “Supply of Drugs for the year 2024-2026”, vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-218/2024 dated 05/11/2024. Detailed tender document containing eligibility criteria, selection mechanisms, and other terms and conditions are available on the Central Public Procurement Portal; [www.eprocure.gov.in](http://www.eprocure.gov.in) and PMBI Website; [www.janaushadhi.gov.in](http://www.janaushadhi.gov.in).

The following amendment in the Tender Document is hereby authorized through Part A and Part B: -

#### Part- A

Sr. No.	Tender Clause/ Reference	Queries/ Suggestions	Clarification/ Amendment
1	Tender Clause 3.U (Eligibility Criteria) at page 10 of the tender document	Bidders have requested to relax the submission of set of Batch Manufacturing Record (BMR) with Technical Bid (Cover-A), whereas some other intending bidders have requested that they be allowed to submit the aforementioned documents after the contract is awarded.	<u>No Change</u> Tender condition prevails.
2	Tender Clause 4.A (General Conditions) at page 12 of the tender document	Bidder has requested to exempt the tender condition ‘Non-local supplier whose local content is less than or equal to 50% shall not be eligible for participating in the tender process.’ for Drug Code DC-92 (Doxycycline Capsules IP 100mg)	<u>No Change</u> Tender condition prevails.
3	Clause 3: I: ELIGIBILITY CRITERIA (Technical Bid -Cover “A”): at page 9 of the tender document.	Some of the intending bidders during pre-bid meeting and over mail (pre-bid query) have requested to reduce the requirement of annual average turnover for three consecutive years of the last four financial years from Rs. 50 Crores (Fifty crores).	<u>No Change</u> Tender condition prevails.

**Part – B**

The following Amendment in Specification is hereby authorized: -

Sl. No	Tender Clause/ Reference	Drug Code	Generic Name of the Drug	Detailed Specification	Unit Size	Bidders Query	Amendment
1	Clause 18.M Annexure-XII	54	Cefixime Tablets IP 100 mg	Each film coated tablet contains: Cefixime Trihydrate IP eq. to Cefixime Anhydrous 100mg	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
2	Clause 18.M Annexure-XII	250	Montelukast Sodium Tablets IP 5mg	Each uncoated chewable tablet contains: Montelukast Sodium IP eq. to Montelukast 5mg	10's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
3	Clause 18.M Annexure-XII	260	Salbutamol Tablets IP 4 mg	Each uncoated tablet contains: Salbutamol Sulphate IP eq. to Salbutamol 4mg	10's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
4	Clause 18.M Annexure-XII	285	Amlodipine 5mg and Lisinopril 5mg Tablets IP	Each Film coated tablet contains: Amlodipine Besilet IP equivalent to Amlodipine 5mg Lisinopril IP Eqv. to Anhydrous Lisinopril 5mg	15's	Bidder requested to amend the detailed specification and pack size of the drug	<b><u>No Change</u></b> Tender condition prevails.
5	Clause 18.M Annexure-XII	290	Metoprolol Tablets IP 25 mg	Each uncoated tablet contains: Metoprolol Tartarate IP 25mg	10's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
6	Clause 20.B & 21.A, Annexure-XIII	360	Mifepristone Tablets IP 200 mg	Each Film-coated tablet contains: Mifepristone IP 200mg	1's	Bidder has requested to amend the packing type	The packaging type is hereby amended as Blister
7	Clause 18.M Annexure-XII	380	Clarithromycin Tablets IP 500 mg	Each Film coated tablet contains: Clarithromycin IP 500mg	4's	Bidder requested to amend the unit size and pack size of the drug	<b><u>No Change</u></b> Tender condition prevails.
8	Clause 18.M Annexure-XII	387	Terbinafine Tablets IP 250mg	Each Uncoated tablet contains: Terbinafine Hydrochloride IP equivalent to Terbinafine 250mg	7's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
9	Clause 18.M Annexure-XII	429	Atorvastatin 10mg and Fenofibrate 160mg Tablets IP	Each film-coated tablet contains: Atorvastatin Calcium IP equivalent to	15's	Bidder requested to amend the unit size of drug	<b><u>No Change</u></b> Tender condition prevails.

				Atorvastatin 10mg Fenofibrate 160mg			
10	Clause 18.M Annexure-XII	457	Torsemide Tablets IP 20 mg	Each uncoated tablet contains: Torsemide IP 20mg	10's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
11	Clause 20.B & 21.A, Annexure-XIII	514	Chymotrypsin and Trypsin (1:6) Tablets 100K AU	Each enteric-coated tablet contains: 1,00,000 armour enzymatic activity (supplied by purified concentrate which has specific Trypsin and Chymotrypsin activity in ratio of approximately six to one)	20's	Bidder has requested to amend the packing type	The packaging type is hereby amended as Blister
12	Clause 18.M Annexure-XII	523	Naproxen Tablets IP 500 mg	Each uncoated tablet contains: Naproxen IP 500mg	15's	Bidder requested to amend the unit size of drug	<b><u>No Change</u></b> Tender condition prevails.
13	Clause 18.M Annexure-XII	568	Salmeterol 25mcg and Fluticasone Propionate 250mcg Inhaler IP	Each actuation delivers: Salmeterol (as Salmeterol Xinofate) 25mcg Fluticasone Propionate IP 250mcg	100 MDI	Bidder requested to amend the unit size of the drug	Unit size of the drug is hereby amended as follows: 120 MDI
14	Clause 18.M Annexure-XII	613	Diclofenac Potassium 50mg, Paracetamol 325mg and Serratiopeptidase 10mg Tablets	Each film-coated tablet contains: Diclofenac Potassium 50 mg Paracetamol 325 mg Serratiopeptidase 10mg (20,000 serratiopeptidase unit as enteric coated granules)	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
15	Clause 20.B & 21.A, Annexure-XIII	917	Imipramine Hydrochloride Tablets IP 25mg	Each film-coated tablet contains: Imipramine Hydrochloride IP 25mg	10's	Bidder has requested to amend the packing type	<b><u>No Change</u></b> Tender condition prevails.
16	Clause 18.M Annexure-XII	944	Levosambutamol Inhaler 50mcg	Each actuation delivers: Levosambutamol tartrate equivalent to Levosambutamol 50mcg	200 MDI	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
17	Clause 20.B & 21.A, Annexure-XIII	1088	Trimetazidine Hydrochloride Modified Release Tablets 35 mg	Each film-coated modified release tablet contains: Trimetazidine Hydrochloride 35 mg	10's	Bidder has requested to amend the packing type of drug	<b><u>No Change</u></b> Tender condition prevails. However, packaging type such as Alu-Alu instead of blister may be accepted.

18	Clause 18.M Annexure-XII	1131	Natural Micronised Progesterone Capsules 200mg	Each soft gelatin capsule contains: Progesterone IP 200mg (Natural Micronised)	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
19	Clause 18.M Annexure-XII	1156	Metoprolol Succinate 25mg (Extended Release) and Amlodipine Besilate 5mg Tablets IP	Each film-coated bilayered tablet contains: Metoprolol Succinate IP equivalent to Metoprolol Tartarate 25 mg (as extended-release form) Amlodipine besylate IP equivalent to Amlodipine 5 mg	7's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
20	Clause 18.M Annexure-XII	1255	Acebrophylline 200mg (Sustained Release) and Montelukast 10mg Tablets	Each film coated bilayered tablet contains: Montelukast Sodium IP equivalent to Montelukast 10 mg (in immediate release form) Acebrophylline 200 mg (in sustained release form)	10's	Bidder requested to amend the detailed specification of drug	<b><u>No Change</u></b> Tender condition prevails.
21	Clause 18.M Annexure-XII	1297	Ranitidine 150mg and Domperidone 10mg Tablets	Each film coated tablet contains: Ranitidine Hydrochloride IP 150mg Domperidone IP 10mg	15's	Bidder requested to amend the unit size of drug	<b><u>No Change</u></b> Tender condition prevails.
22	Clause 18.M Annexure-XII	1302	Duloxetine Gastro- resistant Tablets IP 20 mg	Each enteric coated tablet contains: Duloxetin Hydrochloride IP eq. to Duloxetin 20mg	10's	Bidder requested to amend the detailed specification of drug	<b><u>No Change</u></b> Tender condition prevails.
23	Clause 18.M Annexure-XII	1312	Flavoxate Tablets IP 200 mg	Each film coated tablet contains Flavoxate Hydrochloride IP 200 mg	15's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
24	Clause 18.M Annexure-XII	1489	Acebrophylline 100mg and Acetylcysteine 600mg Tablets	Each film coated bilayer tablet contains: Acebrophylline 100 mg Acetylcysteine 600mg	10's	Bidder requested to amend the detailed specification of drug	<b><u>No Change</u></b> Tender condition prevails.
25	Clause 20.B & 21.A, Annexure-XIII	1498	Acotiamide Tablets 100mg	Each Film Coated tablet contains: Acotiamide Hydrochloride Hydrate 100mg	10's	Bidder has requested to amend the packing type	The packaging type is hereby amended as Blister

26	Clause 18.M Annexure-XII	1501	Amantadine Hydrochloride Capsules IP 100 mg	Each hard gelatin capsule contains: Amantadine Hydrochloride IP 100 mg	10's	Bidder requested to amend the unit size and detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
27	Clause 18.M Annexure-XII	1537	Calcium and Vitamin D3 Capsules	Each soft gelatin capsule contains: Calcium Carbonate 1250 mg (equivalent to elemental Calcium 500 mg) Cholecalciferol (Vitamin D3) 500 IU	10's	Bidder requested to amend the detailed specification of drug	<b><u>No Change</u></b> Tender condition prevails.
28	Clause 18.M Annexure-XII	1696	Linagliptin Tablets 5mg	Each Film Coated tablets contains: Linagliptin 5mg	10's	Bidder requested to amend the unit size and detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
29	Clause 18.M Annexure-XII	1780	Rivaroxaban Tablets 10mg	Each Film Coated tablet contains: Rivaroxaban 10mg	30's	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
30	Clause 18.M Annexure-XII	1821	Tiotropium Bromide Inhalation 9mcg per actuation	Each actuation delivers: Tiotropium Bromide Monohydrate IP equivalent to Tiotropium 9 mcg	200 MDI	Bidder requested to amend the unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.
31	Clause 18.M Annexure-XII	2019	Metformin Hydrochloride 1000mg (Prolonged release) and Glimepiride 3mg Tablets IP	Each Film coated bilayered Tablet contains: Glimepiride 3 mg Metformin Hydrochloride 1000 mg (As Prolonged-release form)	10's	Bidder requested to amend the detailed specification of drug	<b><u>No Change</u></b> Tender condition prevails.
32	Clause 18.M Annexure-XII	2099	Dapagliflozin 10mg and Metformin Hydrochloride (Extended Release) 1000mg Tablets	Each film coated bilayered tablet contains: Metformin Hydrochloride 1000mg (as extended-release form) Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 10 mg	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.

33	Clause 18.M Annexure-XII	2100	Dapagliflozin 10mg and Metformin Hydrochloride (Extended Release) 500mg Tablets	Each film coated bilayered tablet contains: Metformin Hydrochloride 500mg (as extended-release form) Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 10 mg	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
34	Clause 18.M Annexure-XII	2111	Isotretinoin Capsules IP 10mg	Each hard gelatin capsule contains: Isotretinoin 10mg	10's	Bidder requested to amend the detailed specification, unit size and packaging type of the drug	The detailed specification of Drug Code DC-2111 is hereby amended as follows: Each soft gelatin capsule contains: Isotretinoin 10mg Unit Size: 10's Packing type: Blister
35	Clause 18.M Annexure-XII	2132	Pregabalin (Sustained release) 75mg and Methylcobalamin 1500mcg Tablets	Each uncoated bilayered tablet contains: Pregabalin IP 75mg (as sustained-release form) Methylcobalamin IP 1500mcg	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails.  However, formulations such as film-coated bilayered instead of uncoated bilayered form may be accepted.
36	Clause 18.M Annexure-XII	2156	Bilastine 20mg Montelukast 10mg Tablets	Each film coated tablet contains: Bilastine 20mg Montelukast Sodium eq. to Montelukast 10mg	10's	Bidder requested to amend the detailed specification of the drug	<b><u>No Change</u></b> Tender condition prevails. However, formulations such as film-coated bilayered instead of film coated form may be accepted.
37	Clause 18.M Annexure-XII and Clause 20.B & 21.A, Annexure-XIII	2363	Sitagliptin 100mg and Metformin 1000mg Extended-Release Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride 1000mg (As Extended-release form)	10's	Bidder requested to amend the detailed specification and packaging specification of the drug	<b><u>No Change</u></b> Tender condition prevails.
38	Clause 18.M Annexure-XII and Clause	2364	Sitagliptin 50mg and Metformin 500mg	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin	10's	Bidder requested to amend the detailed specification and	<b><u>No Change</u></b> Tender condition prevails.

	20.B & 21.A, Annexure-XIII		Extended-Release Tablets	50mg Metformin Hydrochloride 500mg (As Extended-release form)		packaging specification of the drug	
39	Clause 18.M Annexure-XII	2537	Diclofenac Sodium 2% w/v, Methyl Salicylate 10% w/v, Menthol 5%, Absolute alcohol 10% v/v Spray	Composition: Diclofenac Sodium 2% w/v, Methyl Salicylate 10% w/v, Menthol 5% w/v, Absolute alcohol 10% v/v	50ml Container	Bidder requested to amend the detailed specification of the drug	The detailed specification of drug is hereby amended as follows: Composition: Diclofenac Sodium 2% w/v, Methyl Salicylate 10% w/v, Menthol 5% w/v, Absolute alcohol 10% v/v In topical solution base (Non-aqueous)
40	Clause 18.M Annexure-XII	2655	Vildagliptin 50mg and Metformin Hydrochloride (sustained release) 1000mg Tablets	Each uncoated bilayered tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg (As Sustained release)	15's	Bidder requested to amend the detailed specification and unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.  However, formulations such as film-coated bilayered instead of uncoated bilayered form may be accepted.
41	Clause 18.M Annexure-XII	2656	Sitagliptin 50mg and Metformin 500mg Extended-Release Tablets	Each uncoated bilayered tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg (As Sustained release)	15's	Bidder requested to amend the detailed specification and unit size of the drug	<b><u>No Change</u></b> Tender condition prevails.  However, formulations such as film-coated bilayered instead of uncoated bilayered form may be accepted.
42	Clause 18.M Annexure-XII	1799	Sitagliptin Tablets 5mg	Each film coated tablet contains: Sitagliptin Hydrochloride eq. to Sitagliptin 5mg	10's	Bidder has requested to amend the generic name and detailed specification of the drug.	The Generic Name & Detailed specification is hereby amended as follows: <b>Generic Name:</b> Saxagliptin tablets (5mg) <b>Detailed specification:</b>

							Each film coated tablet contains: Saxagliptin Hydrochloride eq. to Saxagliptin 5mg
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**\*\*Note:**  
If bidder offers advance packaging over the tender requirement, it shall be accepted. (e.g., Packing of ALU-ALU shall be accepted in case of blister is required as per tender.)

**All other contents of the tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and conditions of the tender document including Amendment No. 1 dated 25/11/2024 and this Amendment No. 2 dated 29/11/2024.**

**Sd/-**  
DGM (Procurement & Quality)  
For & on behalf of PMBI  
Ph: 011-49431800 (811)