

Order

Tender No. BPPI/ Drug/RC-150/2020

Date- 16 /11/2021

Whereas, Pharmaceuticals and Medical Devices Bureau of India, New Delhi had published tender no. BPPI/ Drug/RC-150/2020 dated 04.04.2020 through e-procurement system i.e., CPP Portal for supply of drugs for one year. **M/s Mascot Health Series Pvt. Ltd., Plot No. 79,80, Sector-6A. IIE, Sidcul, Haridwar (U.K.)-249403, India** (hereafter called as the firm) had participated in the tender.

The firm was awarded for Drug code 779, Alpha Lipoic Acid 100mg, Vitamin D3 1000IU, Folic Acid 1.5mg, Pyridoxine 3mg and Methylcobalamin1500mcg Tablets supplied to PMBI for the period of one years as per tender provision. Samples of Drug Code-779, below batches were declared as **“NOT OF STANDARD QUALITY”** after testing in Empaneled NABL and joint testing by another NABL. The samples declared misbranded as per the Drugs & Cosmetics Act and Rules 1945. The details of quality check report of various batches of said drug is given herein below: -

Product Name	Batch No.	Purchase Invoice No.	Exp. Date	Reason of rejection	Failed by	Action taken by PMBI
DC 779 Alpha Lipoic Acid 100mg, Vitamin D3 1000IU, Folic Acid 1.5mg, Pyridoxine 3mg and Methylcobalamin1500m cg Tablets	MT212208	2102000632 dated 07.05.2021	06/23	The Sample Fails in Assay test of Vitamin D3	Empaneled NABL of PMBI	Show Cause Notice & Debit Note
	MT212209					
	MT212210					
	MT212211					
	MT212212					
MT212213						

In view of the test reports obtained from Empaneled Laboratories, show cause notices was issued to the firm on 20.10.2021 informing about the terms outlined in tender provisions of the clause no. 22 D, 27B, 26D & 27A of tender document with request to explain within 7 days why not following actions against them may be taken: -

- (i) Forfeiture of Security Deposit submitted by them as per clause 26 (D) of tender document.
- (ii) Blacklisting/debarring of the firm as per clause 26 (C) & 27 (A) of tender document.

In response to the show cause notice, the firm informed by their Ref. Letter No. MAS/RC-150/2020/C-1 dated 31.10.2021 that not to take further action on them as per process of law and any action thereof would be result in grave travesty of justice.

As evident from the analysis report received in Form-39A, all the six batches manufactured and supplied from M/s Mascot Health Series Pvt. Ltd. were found to be “Not of Standard Quality”. Also, after joint testing in another Empaneled NABL, the results were failing, and the samples are deemed to be misbranded as per the Drugs and Cosmetics Act 1940 and Rules made there under.

In view of the above facts, it is explicitly clear that the reply given by the firm is not considered and the reports received from two empaneled NABL is conclusive, final and binding on the suppliers.

So, in exercise of the provision contained in clause no. 27 A of tender document which is reads as under: -

"27 (A)"If the Tenderer fails to perform the obligations under the tender conditions / commits default in the performance of the contract/LOA, such Tenderers will be blacklisted for a period of 2 years by BPPI from the date of intimation besides forfeiture of EMD/ Performance Guaranteee."

In view of above, the firm **M/s Mascot Health Series Pvt. Ltd.** is debarred for a period of two (2) successive years to participate in any tender of PMBI for supplying of drug i.e., **Drug Code 779 Alpha Lipoic Acid 100mg, Vitamin D3 1000IU, Folic Acid 1.5mg, Pyridoxine 3mg and Methylcobalamin1500mcg Tablets** from date of issuance of this order and liable for recovery of total cost of NSQ batches as per clause no. 22 D, 26 C, 26 D & 27 A.

This order is without prejudice to the legal and criminal action to be taken if any, by Pharmaceuticals and Medical Devices Bureau of India, New Delhi in the matter.



16/11/28

Parth Gautam Sharma, IRS
Dy. Chief Executive Officer
Pharmaceuticals and Medical Devices Bureau of India, New Delhi

To

M/s Mascot Health Series Pvt. Ltd.
Plot No.. 79,80, Sector—6A. IIE,
Sidcul, Haridwar (U.K.)-249403
India.