

No. BPPI/Drug- 025/2015

Dated: 26/11/2018

Order

Whereas, Bureau of Pharma Public Sector Undertakings of India, New Delhi had published tender no. BPPI/Drugs- 025/2015 dated 18.12.2017 through open tender system for supply of drugs for the year 2015-2017.

Whereas, **M/S Mascot Health Series Pvt Ltd (here after called as the firm) address of office at 75,76,77 2nd Floor, LSC (DDA Market, J-Block, Vikaspuri, New Delhi and manufacturing address Plot no 79, 80 Sec-6A, I.I.E., SIDCUL, Haridwar-249403** had participated in the tender. The firm was awarded 09 drugs by BPPI, New Delhi for the period of 2 years as per tender provision. **Samples of Diltiazem Tablets SR 90mg Drug code 425 and Ramipril 5mg with Hydrochlorothiazide 12.5mg Tablets Drug code 431 found NOT OF STANDARD QUALITY** after testing in Government lab as per details below:

Product Name	Batch No.	Mfg. Date	Exp. Date	Reason of rejection	Failed by	Report no.
Diltiazem Tablets SR 90mg Drug code 425	MT16 1467	12/16	11/18	Drug not found in SR form	Drug inspector, Pathanamthitta, Kerala	SW/4759/2017/DTL Dated 08/11/2017
Ramipril 5mg with Hydrochlorothiazide 12.5 mg Tablets Drug code 431	MT17 0883	07/17	06/19	Fail in assay of ramipril	Drug inspector, Shimoga, Karnataka	1451-HUB-17-18/I-1-1739 dt 14/6/2018

Whereas, Bureau of Pharma Public Sector Undertakings of India, New Delhi issued Show cause notice on dt 25/09/2018 to the firm informing about provisions of the clause no. 15.2, 19.2 & 20.1(a) of tender document with request to explain within 7 days why not following actions against them may be taken:-

- (i) Recover the amount of Rs 76558.00 from supplier through demand draft and not to be release any outstanding payment of same supplier until recovery has to make.
- (ii) Initiate blacklisting of your company.

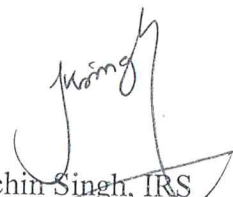
Whereas, the firm vide their letter dated 01/10/2018 informed that their control samples of above drugs comply with all quality standard. They further stated that the sample may be tested as per procedure provided by the manufacturer. In this regard it was noted from the Govt Laboratory protocol forwarded by Drug Inspector, Pathanamthitta, Kerala that shows "Diltiazem Tablets are official in IP, but it is not mentioned in the label. As per IP, Diltiazem tablets may be modified release tablets and separate procedure for dissolution test of modified release tablets is given in the monograph".

M/s Mascot informed us via mail 25 Oct 2018 that Ramipril 5 mg and hydrochlorothiazide 12.5 mg tested through Shri Ram institute for industrial research, found complies results, taken 23 days while normally tablets assay results came in 2 to 3 days maximum.

And Shri Ram institute for industrial research is not government laboratory, So, the explanation of firm is unjustified and not acceptable. Therefore, the reports received from the Government Drug Testing Laboratory will be conclusive and final and binding on the suppliers in terms of provision of clause 20.2.1 (f) of tender document.

In view of above, **M/S Mascot Health Series Pvt Ltd.** is debarred for a period of 2 years to participate in any tender of BPPI for supplying of two drugs i.e. **Diltiazem Tablets SR 90mg and Ramipril 5mg with Hydrochlorothiazide 12.5mg Tablets** from date of issuance of this order besides forfeiture of performance security.

This order is without prejudice to the legal and criminal action to be taken if any, by Bureau of Pharma Public Sector Undertakings of India, New Delhi in the matter.



Sachin Singh, IRS
Chief Executive Officer
For & on Behalf of BPPI, New Delhi

To

M/S Mascot Health Series Pvt Ltd. HO 75,76,77 2nd Floor, LSC (DDA Market),
J-Block, Vikaspuri, New Delhi-110018