No. BPPI/Drug- 40.2/2017

Order

Dated: 04/10/2019

Whereas, Bureau of Pharma Public Sector Undertakings of India, New Delhi had published tender no. BPPI/Drugs- 40.2/2017 through e-procurement system i.e CPP Portal for supply of drugs for the year 2017-2019.

Whereas, M/s Scott-Edil Pharmacia Ltd, M/s Scott - Edil Pharmacia Ltd, '54-55, Industrial Area Phase-II, Chandigarh – 160002' had participated in the tender. The firm was awarded Drug code 39 Amoxicillin 500mg and Clavulanic acid 125mg tablets supply to BPPI, New Delhi for the period of 2 years as per the tender provision. Sample of awarded Drug code 39 Amoxicillin 500mg and Clavulanic acid 125mg tablets Batch no. SB58049 & SB58042 were found NOT OF STANDARD QUALITY after market complaint and testing in Government laboratory as per details below:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Batch No.</th>
<th>Mfg. Date</th>
<th>Exp. Date</th>
<th>Reason of rejection</th>
<th>Failed by</th>
<th>Report No.</th>
<th>Action taken by BPPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin 500mg and Clavulanic acid 125mg</td>
<td>Batch no: SB58049 &amp; SB58042</td>
<td>03/18</td>
<td>02/20</td>
<td>Market Complaint: Tablet strips get swell</td>
<td>BPPI Quality Team</td>
<td>NA</td>
<td>Recall and stop sale and distribution</td>
</tr>
<tr>
<td>Amoxicillin 500mg and Clavulanic acid 125mg</td>
<td>Batch no: SB58049</td>
<td>03/18</td>
<td>02/20</td>
<td>Failing in dissolution and assay</td>
<td>Government Analyst</td>
<td>RDTL/GB/16532/N G/13005/18-19/4666</td>
<td>RDTL Guwahati</td>
</tr>
</tbody>
</table>

Whereas, Bureau of Pharma Public Sector Undertakings of India, New Delhi issued Show cause notice on dt 24/01/2019 and 19/07/2019 to the firm informing about provisions of the clause no. 15.2, 19.2 & 20.1(a) of tender document with respect to explain within 7 days why not following actions against them may be taken:

(i) Recovery of NSQ batches amount as per clause 15.2 and 19.2, as per tender document.
(ii) blacklisting/debarring of the firm as per clause 19.2 and 20.1(a) of tender document.

Whereas, the firm vide their letter dated 11/02/2019 informed that market complaint arises due to improper storage condition. Thereafter batch no. SB58049 failed in dissolution as well as in assay by government analyst, show cause has given on dated 19/07/19, but no reply received from firm side. The Explanation of the firm is not acceptable as the reports received from the Government Drug Testing Laboratory will be conclusive, final and binding on the suppliers in terms of provision of clause 20.2.1 (f) of tender document.

In view of above, the firm is debarred for a period of 2 years to participate in any tender of BPPI for supplying of drug i.e. Amoxicillin 500mg and Clavulanic acid 125mg tablets from date of issuance of this order and liable for recovery of total cost of NSQ batches.

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 Scott - Edil Pharmacia Ltd, '54-55, Industrial Area Phase-II, Chandigarh – 160002'

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