

File No.: - BMSIC/40010/53-2023/ 4391

Date: 25/07/2025

Order

M/s **Pushkar Pharma** situated at Bhandariwala, Kheri, Kala-Amb-173030, District-Sirmour, HP, has participated in tender reference no. - BMSIC/DRUGS/23-03 and was issued a Letter of Intent (LoI) vide letter no.- 5448 dated 27.09.2023 for submitting the requisite documents, security deposit, and to execute the Rate-Contract within 10 days from the date of receipt of the LoI for **Clotrimazole Ear Drop 1% w/v 5ml bottle**.

The firm signed an agreement with BMSICL on 03.01.2024. Subsequently, M/s **Pushkar Pharma** was issued Purchase Orders for **Clotrimazole Ear Drop 1% w/v 5ml bottle** vide P.O. No. 10282401562 dated 20-07-2024.

The following batches of **Clotrimazole Ear Drop 1% w/v 5ml bottle** supplied to the Patna, Purnea, and Muzaffarpur warehouses of BMSICL against the above-mentioned Purchase Orders, were declared 'Not of Standard Quality' (NSQ) by BMSICL-empanelled Quality Testing Laboratories and Batch No. CLT-214A was declared NSQ by CDL, Kolkata.

S.No.	Name of the Drug	Batch No.	Report	Reason of NSQ
1.	Clotrimazole Ear Drop 1% w/v 5ml bottle.	CLT-219A	NSQ by BMSICL Empanelled Laboratory.	Failed in Assay parameter.
2.		CLT-217A		
3.		CLT-214A	NSQ by BMSICL Empanelled Laboratory & CDL, Kolkata	

BMSICL issued Show Cause Notices to the firm vide Letter Nos. 9503 dated 14.01.2025 and 3596 dated 08.07.2025. The firm submitted a reply via email dated 17.07.2025, stating only that they are initiating a product recall for Batch No. CLT-214A due to a technical reason. No response was provided regarding the NSQ. However, upon examination, the reply was found to be unsatisfactory.

In order to ensure quality products for the people of State of Bihar, BMSICL asks for test/analysis reports furnished by independent NABL Accredited Drugs Testing Laboratory/Central Drug Testing Laboratory/In House Quality Control Laboratory of all the batches of the Drugs supplied.

To ensure the quality of products for the people of the State of Bihar, post-shipment quality testing is also carried out by BMSICL, particularly for the procurement of drugs. The objective of post-shipment quality testing is to confirm that the drugs received by BMSICL meet the required quality standards for their intended use. This ensures compliance with the standards set by the procurement agency. As per Clause 24(c) of the Bid Document, "Random samples of each supplied batch will be chosen at the point of supply or distribution/storage points for testing. The samples will be sent to different BMSICL-empanelled laboratories."

2. As per Clause 20(a) of the Bid Document, "The drugs supplied by the successful bidder shall be of the Standard Quality and shall comply with the specifications, stipulations and conditions specified under Drugs and Cosmetics Act and Rules there under and also should confirm to Terms and Conditions laid down in NIT and Rate Contract/agreement"

3. As per Clause 24(c) of Bid Document, "Random samples of each supplied batch will be chosen at the point of supply or distribution/storage points for testing. The samples will be sent to different BMSICL empanelled laboratories."




4. Clause 24 (e) of the Tender Document is relevant for such cases which read as follows: *"The Drugs shall be of standard quality throughout the shelf life period of the item. Samples can be drawn for quality testing periodically throughout the shelf life period. If the sample is declared to be "NOT OF STANDARD QUALITY" or spurious or adulterated or misbranded, such batch / batches will be deemed to be rejected goods and action will be taken as per tender clause."*

5. Clause 24(f) of the Tender Document is relevant for such cases which reads as follows: *"If the product/sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period"*.

6. Clause 24 (g) of the Tender Document is relevant for such cases which reads as follows: *"If a sample is found as not of standard quality by the Tender Inviting Authority, the distribution of NSQ batch will be frozen. The bidder will be liable for appropriate action as per the tender conditions and also for other legal actions under the Drugs & Cosmetics Act & Rules. The Tender Inviting Authority, at his discretion may terminate the Contract and in case of such termination, the supplier shall be liable for all losses sustained by the Tender Inviting Authority, which may be recovered from the Security Deposit made by the Supplier and / or any other money due or becoming due to him. In the event of such amounts being insufficient, the balance may be recovered from the Supplier as per the provisions of Law."*

7. Clause 27 B (1) of the Tender Document is relevant for such cases which read as follows: *"Each and every batch of Drugs supplied by the supplier shall be subjected to quality test by the Empanelled laboratories as per the procedure adopted by BMSICL."*

8. Clause 27 B (3) of the Tender Document is relevant for such cases which reads as follows: *"If 3 batches of a particular item supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and /or other parameters, then the particular item of the firm shall be blacklisted for minimum of two years besides forfeiture of Security Deposit of that particular product(s)."*

9. Clause 27(C) of the Tender Document is relevant for such cases which reads as follows: *"The blacklisting of particular product or company/firm will be done without prejudice to other penalties which may be imposed as per the conditions of Tender documents and also to other actions which may be initiated under Drugs and Cosmetics Act, 1940 or any other law of Land. BMSICL will display names of such blacklisted product(s) and company/firm on its website for general notice."*

10. Clause 2(b) & 2(g) of the agreement mentions that the complete tender document shall be deemed to form and be read and construed as part of this agreement, and as per Clause 5 (k) of the standard bid document, *"affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure IV."* The firm has submitted the concerned affidavit regarding acceptance of tender conditions in Annexure IV. The sample was sent for analysis as per Clause 24 (a) and (c) of the Bid document. As per Clause 27(B) (3) of the Bid document, 3 batches have been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories and Batch No. CLT-214A was declared NSQ by CDL, Kolkata.

Thus, in light of the provisions contained in the Tender Document & contract agreement, the firm **M/s Pushkar Pharma**, located at Bhandariwala, Kheri, Kala-Amb-173030, District-Sirmour, HP, is hereby blacklisted for the quoted product, **Clotrimazole Ear Drop 1% w/v 5ml bottle**, for a period of two (02) years, effective from the date of issuance of this order. This action follows the findings that the assay of Clotrimazole Ear Drop 1% w/v 5ml bottle. Furthermore, the security deposit for the aforementioned product shall be forfeited, and all unexecuted purchase orders issued previously shall be considered cancelled.


(Managing Director)

