

File No.:- BMSIC/40010/43-2023/4/06

Date: -/8/07/2025

Order

M/s Affy Parenterals situated at N-101, Anupam Apartment, East Arjun Nagar, Delhi-110032 has participated in tender reference no.- BMSIC/DRUGS/23-03 and was issued a Letter of Intent (LoI) vide letter no.- 5443 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 LoI for the product **Cholecalciferol Powder 60000 IU Sachet.**

The firm signed an agreement with BMSICL on 17.10.2023. Subsequently, M/s Affy Parenterals was issued Purchase Orders for Cholecalciferol Powder 60,000 IU Sachet vide P.O. No. 6932 dated 09-11-2023, 10282401683 dated 22-07-2024.

The following batches of Cholecalciferol Powder 60,000 IU Sachet, supplied to the Patna, Purnia and Muzaffarpur warehouses of BMSICL against the above-mentioned Purchase Orders, were declared 'Not of Standard Quality' (NSQ) by BMSICL-empanelled Quality Testing Laboratories. Additionally, Batch Nos. TPD24015, TPD24018, TPD24019, and TPD24020 were also declared NSQ by CDL Kolkata.

S. No.	Name of the Drug	Batch No.	CDL Report	Reason of NSQ
1.	Vitamin D Cholecalciferol granules as 60000 IU/g in sachets.	TPD24015	NSQ by BMSICL Empanelled Laboratory & CDL Kolkata	Failed in Assay of Vitamin D3 Parameter.
2.		TPD24018		
3.		TPD24019		
4.		TPD24020		
5.		TPD24021	BMSICL Empanelled Laboratory	
6.		TPD24022		
7.		TPD24029		
8.		TPD24031		
9.		TPD24027		
10.		TPD24034		
11.		TPD24035		
12.		TPD24038		
13.		TPD24040		

BMSICL issued Show Cause Notices to the firm vide Letter No. 7854 dated 03.12.2024, 8913 dated 31-12-2024, 9502 dated 14-01-2025, 10284 dated 29-01-2025, 11565 dated 03-03-2025 & 1730 dated 19.05.2025, regarding the above-mentioned failed batches of Vitamin D (Cholecalciferol) Granules 60,000 IU/g in sachets. The firm submitted reply dated 04.02.2025; however, upon examination, it was found to be unsatisfactory. The firm mentioned that they tested their control sample, which passed all the test parameters. The firm also accepted test results & assured to replace the NSQ stock available at BMSICL warehouses.

BMSICL-empanelled quality testing laboratories conduct drug tests as per the monographs specified in the Indian Pharmacopoeia (I.P.), and the methods used by the laboratories are in alignment with I.P. standards. 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."

Timely supply of good-quality drugs, involving both procurement and logistics management, is critically important to the health system of the State of Bihar. To ensure the availability of quality products for the people of Bihar, BMSICL requires a Certificate of Analysis from an NABL-accredited Drug Testing Laboratory, Central Drug Laboratory, or In-House Quality Control Laboratory, along with the necessary protocols for every batch of items supplied with the consignment.

In addition to pre-shipment testing, post-shipment quality tests are also mandatory, particularly in the case of drug procurement. The objective of post-shipment quality testing is to ensure that the drugs received by BMSICL meet the required standard of quality for their intended use. This process ensures that the drugs comply with the standards set by the procurement agency.

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 reads 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 reads as follows: "Each and every batch of Drugs supplied by the supplier shall adopted by BMSICL."

8. Clause 27 B (2) of the Tender Document is relevant for such cases which reads as follows: "If such sample fails in quality test for ASSAY content of less than 50% as per the Government Analyst report, such product of the supplier will be de-registered/debarred for one year.

9. 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)."

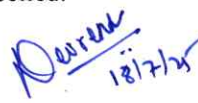
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10. Clause 27(C) of the Tender Document is relevant for such cases which reads as follows: “The blacklisting of particular product or company/firm will be done without prejudice to other penalties which may be imposed as per the conditions of Tender 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.”

11. 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, 13 batches have been declared as ‘Not of Standard Quality’ by the BMSICL-empanelled Quality Testing Laboratories, out of which 4 batches were declared NSQ by CDL, Kolkata.

Thus, in light of the provisions contained in the Tender Document, the firm M/s Affy Parenterals, located at N-101, Anupam Apartment, East Arjun Nagar, Delhi-110032, is hereby blacklisted for its quoted product, **Cholecalciferol Powder 60,000 IU Sachet**, for a period of two (02) years from the date of issuance of this order. Additionally, the security deposit for the said product shall be forfeited. All unexecuted Purchase Orders issued earlier shall also stand cancelled.


(Managing Director)

