

File No.: - BMSIC/40010/77-2023/ 4107

Date: 18/07/2025

Order

M/s Affy Parenterals situated at N-101, Anupam Apartment, East Arjun Nagar, Delhi-110032 has participated in Tender reference no.- BMSIC/DRUGS/23-07 and was issued a Letter of Intent (LoI) vide letter no.- 5819 dated 10.10.2023 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 **Cefixime Oral Suspension IP 100mg/5ml 30ml Bottle**.

The firm signed an agreement with BMSICL on 22.11.2023. Subsequently, M/s Affy Parenterals was issued Purchase Orders for **Cefixime Oral Suspension IP 100mg/5ml 30ml Bottle** vide P.O. No. 9977 dated 20.02.2024. The following batches of **Cefixime Oral Suspension IP 100mg/5ml 30ml Bottle**, supplied to the Patna, Purnea, and Muzaffarpur warehouses of BMSICL against the above-mentioned Purchase Order, were declared 'Not of Standard Quality' (NSQ) by BMSICL-empanelled Quality Testing Laboratories.

S.No	Batch No.	Name of the Drug	Reason of NSQ
1.	PD24020	Cefixime Oral Suspension IP 100mg/5ml.	Failed in Assay Parameter.
2.	PD24026		
3.	PD24025		
4.	PD24027		
5.	PD24022		
6.	PD24023		
7.	PD24021		

BMSICL issued Show Cause Notice to the firm vide Letter No. 3458 dated 18.07.2024 regarding the above-mentioned failed batches of **Cefixime Oral Suspension IP 100mg/5ml 30ml Bottle** against which the firm submitted reply dated 25.07.2024; however, upon examination, it was found to be unsatisfactory.

The firm mentioned that they have analysed their control sample and found that Assay is as per I.P pharmacopeia standards. They mentioned that the issue is with the reconstitution of suspension. They also accepted NSQ quality and agreed to replace the stocks of failed batches with fresh stock.

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." Therefore, the provision of Section 23(4) is not applicable in this context.




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 reads 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, more than 3 batches (total 07) have been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

Durva



Thus, in light of the provisions contained in the Tender Document, the **M/s Affy Parenterals** situated at N-101, Anupam Apartment, East Arjun Nagar, Delhi-110032., is hereby blacklisted for its quoted product, **Cefixime Oral Suspension IP 100mg/5ml 30ml Bottle**, 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.

Devi
18/12/24
(Managing Director)

