

File No.: - BMSIC/40035/10-2023/ 7559

Date: 26/09/2025

Order

M/s Hindustan Medicines Pvt. Ltd. situated at Phulawaria Bazar, Barauni-851112, Begusarai Bihar. has participated in tender reference no.- BMSIC/DRUGS/22-15 and was issued a Letter of Intent (LoI) vide letter no.- 1085 dated 17.05.2023 for submitting the requisite documents, security deposit, and to execute the Rate-Contract within 15 days from the date of receipt of the LoI for **Dexamethasone Sodium Phosphate Injection 4 mg/ml.**

The firm signed an agreement with BMSICL on 21.08.2023. Subsequently, **M/s Hindustan Medicines Pvt. Ltd.** was issued Purchase Orders for **Dexamethasone Sodium Phosphate Injection 4 mg/ml.** vide P.O. No. 10282401036 dated 30.04.2024, 10282500192 dated 28.01.2025 & 10282500786 dated 26.03.2025

The following batches of **Dexamethasone Sodium Phosphate Injection 4 mg/ml**, 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. Additionally, Batch No. 119 & 155 of Dexamethasone Sodium Phosphate Injection 4 mg/ml was declared **Not of Standard Quality** by Central Drug Laboratories (CDL) Kolkata, of Govt of India.

S.No	Name of the Drug	Batch No.	CDL Report	BMSICL Lab Report
1.	Dexamethasone Sodium Phosphate Injection 4 mg/ml.	119	Failed in Free Dexamethasone Particulate Matter, Sterility, Extracted volume & Description parameter	Failed in Sterility parameter.
2.		155	Failed in Particulate Matter & Description parameter.	Failed in Assay parameter.
3.		171	NA	Failed in Sterility parameter.

BMSICL issued Show Cause Notices to the firm vide Letter Nos. 9354 dated 10.01.2025, 2804 dated 20.06.2025 & 5202 dated 13.08.2025. The firm submitted reply vide email dated 17-01-2025, 26-06-2025 & 22.08.2025.

The firm stated that the all necessary precaution has been taken in the manufacturing and testing of Drugs. The Drugs in question was properly tested and was found to be of Standard Quality, all the condition were full filled. As per report supplied, drugs passed in all parameter but failed in Assay i.e. 88.75 in place of 95% (lower limit). The firm also mentioned that they had sent the same batch to the NABL Approved lab for reconfirmation and found supplied batch drug passed in all parameter. Firm has replied to show cause in textbook manner and failed to give satisfactory reply on the 3 failed batches, so show cause found unsatisfactory.

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."

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.




It is pertinent to mention relevant clauses of tender document and contract agreement as follow:-

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. A total of 3 (three) Batches have been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

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Thus, in light of the provisions contained in the Tender Document and contract agreement, the firm **M/s Hindustan Medicines Pvt. Ltd.** situated at Phulawaria Bazar, Barauni-851112, Begusarai Bihar, is hereby Blacklisted for its quoted product, Dexamethasone Sodium Phosphate Injection 4 mg/ml. 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)

