

Date: 17/07/2025

Order

M/s Sam Kem. situated at 15-B, AKVN, Industrial Area, Rangwasa, Rao, Indore- 453331, Madhya Pradesh, has participated in tender reference no.- BMSIC/DRUGS/23-14 and was issued a Letter of Intent (LoI) vide letter no.- 8630 dated 15.01.2024 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 **Oral Rehydration Salts IP.**

The firm signed an agreement with BMSICL on 25.01.2024. Subsequently, M/s Sam Kem was issued Purchase Orders for **Oral Rehydration Salts IP.** vide P.O. No. 10282401126 dated 02.05.2024.

The following batches of **Oral Rehydration Salts IP.**, 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.

S.No	Name of the Drug	Batch No.	Date of issue	Reason of NSQ
1.	Oral Rehydration Salts IP.	P24/0651	09.10.2024	Failed in seal test Parameter
2.		P24/0654	09.10.2024	
3.		P24/0657	09.10.2024	
4.		P24/0664	09.10.2024	
5.		P24/0665	09.10.2024	
6.		P24/0671	09.10.2024	
7.		P24/0684	14.10.2024	

BMSICL issued Show Cause Notices to the firm vide Letter Nos. 7853 dated 03.12.2024 and 11198 dated 21.02.2025. The firm submitted reply vide Letter No. 1312 dated 25.02.25 however, upon examination, it was found to be unsatisfactory.

The firm stated that the report lacks an explanation of the test procedure, as mandated by I.P. 2022. It also pointed out that the attached NABL report does not provide a detailed methodology or observations, as required, and that the empanelled laboratory failed to specify how many sachets out of the ten tested were found to have leakage, as per I.P. 2022 requirements. Additionally, the firm referred to Rule 150E (sub-sections F and G) and Sections 21, 22, and 23 of the Drugs and Cosmetics Act, 1940 and 1945, and requested the test report from a government laboratory.

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.

Dwivedi



Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) functions as the nodal procurement agency for Drugs in the state of Bihar. In line with its mandate to ensure transparency, efficiency, and quality in public health procurement, BMSICL floats tenders governed by a comprehensive Standard Bid Document (SBD). Participating firms are required to submit an affidavit affirming acceptance of tender conditions outlined in the SBD. The firm has submitted the concerned affidavit. To uphold the highest standards in public healthcare delivery, the SBD includes specific clauses related to the quality of Drugs. All procured Drugs undergo mandatory quality testing through BMSICL-empanelled testing laboratories. Only those Drugs that successfully pass quality checks are accepted and distributed. This stringent quality assurance mechanism ensures that only safe and effective Drugs reach healthcare institutions across the state. BMSICL has its own established system for the procurement and quality testing of Drugs, as clearly outlined in the Standard Bid Document. Form 39, as referenced in Rule 150E (f) of the Drugs and Cosmetics Rules, 1945, pertains to the report of test or analysis by an approved institution for an individual, organization, or procurement agency. Specifically, it outlines the format for reporting the test results of samples received by the approved institution—whether from manufacturers or from individuals, organizations, or procurement agencies.

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".*

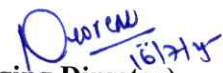
6. Clause 24 (g) of the Tender Document is relevant for such cases which reads as follows: *"If a sample is found as not of standard quality by the Tender Inviting Authority, the distribution of NSQ batch will be frozen. The bidder will be liable for appropriate action as per the tender conditions and 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."*

Thus, in light of the provisions contained in the Tender Document, the firm **M/s Sam Kem.** situated at 15-B, AKVN, Industrial Area, Rangwasa, Rao, Indore-45333, Madhya Pradesh, is hereby Blacklisted for its quoted product, **Oral Rehydration Salts IP.**, 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)

