

File No.: - BMSIC/40025/208-2022/4105

Date: 18/07/2025

Order

M/s **Martin & Brown Bio Sciences Pvt Ltd.** situated at Village-Malkumajra Opp. Anapurna Hotel, PO Bhud, Tehsil Baddi District-Solan-173205. has participated in tender reference no.- BMSIC/DRUGS/22-12 and was issued a Letter of Intent (LoI) vide letter no.- 7600 dated 27.12.2022 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 **Rabeprazole Sodium Gastro Resistant Tablet 20mg.**

The firm signed an agreement with BMSICL on 20.02.2024. Subsequently, M/s **Martin & Brown Bio Sciences Pvt Ltd** was issued Purchase Orders for **Rabeprazole Sodium Gastro Resistant Tablet 20mg** vide P.O. No. 10282400884 dated 29-04-2024.

The following batches of **Rabeprazole Sodium Gastro Resistant Tablet 20mg**, 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 | Report                                             | Reason of NSQ                                                             |
|------|---------------------------------------------|-----------|---------------|----------------------------------------------------|---------------------------------------------------------------------------|
| 1.   | Rabeprazole Gastro Resistant Tablets- 20mg. | MT-24E27  | 31.07.2024    | NSQ by BMSICL Empanelled Laboratory                | Failed in Dissolution & Assay parameter.                                  |
| 2.   |                                             | MT-24E30  | 22.07.2024    | NSQ by BMSICL Empanelled Laboratory & CDL, Kolkata | Failed in Description, Related substances, Dissolution & Assay parameter. |

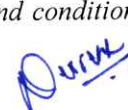
Additionally, Batch No. MT-24E30 of **Rabeprazole Sodium Gastro Resistant Tablet 20mg** was declared **Not of Standard Quality** by CDL, Kolkata on the parameter of test for related substances, dissolution (buffer stage) and Assay of Rabeprazole Sodium. In Assay, Rabeprazole Sodium was found to be 6.52 mg/tablet i.e. 32.6% of the claim. Clause 27 B (2) 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."

BMSICL issued Show Cause Notices to the firm vide Letter Nos. 4134 dated 13.08.2024 and 5002 dated 09.03.2024. A final show cause notice was issued to the firm vide Letter No. 12757 dated 26.03.2025. The firm submitted reply vide email dated 31.08.2024 & 25.09.2024; however, upon examination, it 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."*

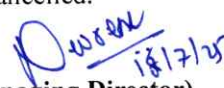
5. Clause 24(f) of the Tender Document is relevant for such cases which reads as follows: *"If the product/sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period"*.

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(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."*

In accordance with Clause 27 B (2) of the Standard Bid Document, which states: *"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"*. M/s Martin & Brown Bio Sciences Pvt Ltd, located at Village-Malkumajra, Opp. Anapurna Hotel, PO- Bhud, Tehsil- Baddi, District- Solan-173205, is hereby de-registered/debarred for the quoted product, **Rabeprazole Sodium Gastro-Resistant Tablets 20mg**, for a period of one (01) year, effective from the date of issuance of this order. This action follows the findings that the assay of Rabeprazole Gastro-Resistant Tablets 20mg, Batch No. MT-24E30, was found to be 6.52 mg/tablet, representing only 32.6% of the claimed assay content. Furthermore, the security deposit for the aforementioned product shall be forfeited, and all unexecuted purchase orders issued previously shall be considered cancelled.

  
(Managing Director)

