

File No.:- BMSIC/40035/47-2023/4002

Date: -/7/ 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/23-01 and was issued a Letter of Intent (LoI) vide letter no.- 2446 dated 28-06-2023 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 **Rabeprazole Sodium For Injection 20mg Dry Powder for Injection Vial**.

The firm signed an agreement with BMSICL on 16-12-2023. Subsequently, **M/s Martin & Brown Bio Sciences Pvt Ltd** was issued Purchase Orders for **Rabeprazole Sodium For Injection 20mg Dry Powder for Injection Vial** vide P.O. No. 8522 dated 11-01-2024, 102824000885 dated 29-04-2024, 10282402317 dated 19-10-2024, 10282501492 dated 20-07-2024, and 10282500306 dated 29-01-2025.

The following batches of **Rabeprazole Sodium for Injection 20mg Dry Powder for Injection Vial**, 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 Sodium For Injection 20mg Dry Powder for Injection Vial.	MD24K19	03.01.2025	NSQ by BMSICL Empanelled Laboratory.	Failed in clarity of solution and/or particulate matter.
2.		MD24E29	15.02.2025		
3.		MD24E32	02.08.2024		
4.		MD25B18	26.05.2025		

Additionally, vide Letter No. 61 dated 07.01.2025, the Indira Gandhi Institute of Cardiology, Patna, reported that Batch No. M024E29 of the product does not mix properly with water for injection and contains suspended particles.

BMSICL issued Show Cause Notices to the firm vide Letter Nos. 5003 dated 11.09.2024, 11070 dated 20.02.2025, 12295 dated 18.03.2025 and 3254 dated 01.07.2025. A final show cause notice was issued to the firm vide Letter No. 12757 dated 26.03.2025, regarding the above-mentioned failed batches of Rabeprazole Sodium For Injection 20mg Dry Powder for Injection Vial. The firm submitted reply vide email dated 23.09.2024, 14.04.2025 and 10.07.2025; however, upon examination, it was found to be unsatisfactory.

The firm mentioned that *"although we have checked and tested our control sample of the said batch and all the parameters within the specified limit as per I.P. 2022. We are enclosing the Re Test CoA for your kind reference."* The firm also mentioned that they have not received any sample portion from BMSICL to compare with their control sample, which is mandatory to be disclosed under Section 18A of D&C Act 1940, under sub Section 23 (4) (iii). The firm also stated that the standards to be complied by Drugs included in I.P will be identity, purity and strength.

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.

In the monograph of I.P., it's mentioned *“The injection is constituted by dissolving the contents of the sealed container in the requisite amount of sterile Water for Injections, immediately before use. The constituted solution complies with the requirements for the Clarify of solution and Particulate matter stated under Parenteral Preparations (Injections).”*

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 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 Martin & Brown Bio Sciences Pvt Ltd, located at Village-Malkumajra Opp. Anapurna Hotel, PO- Bhud, Tehsil- Baddi, District-Solan-173205, is hereby blacklisted for its quoted product, **Rabeprazole Sodium For Injection 20mg Dry Powder for Injection Vial**, 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)

