

File No.: - BMSIC/40010/47-2023/6939

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/23-03 and was issued a Letter of Intent (LoI) vide letter no.- 5429 dated 27.09.2023 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 **Carboxy methyl cellulose Eye Drop 0.5% w/v 10ml Bottle.**

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 **Carboxy methyl cellulose Eye Drop 0.5% w/v 10ml Bottle** vide P.O. No. 9924 dated 20.02.2024, 10282400942 dated 29.04.2024, 10282401543 dated 20.07.2024 & 10282402402 dated 19-10-2024.

The following batches of **Carboxy methyl cellulose Eye Drop 0.5% w/v 10ml Bottle**, 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.N.	Batch No.	Name of the Drug	Reason of NSQ
1	MO24F11	Carboxy methyl cellulose Eye Drop 0.5% w/v 10ml Bottle.	Failed in pH parameter.
2	MO24F14		
3	MO24H22		
4	MO24H17		
5	MO24H28		
6	MO24H27		
7	MO24H21		
8	MO24H23		
9	MO24H19		
10	MO24K20		Failed in description & appearance of solution.

A total of 10 batch reports were found to be NSQ, of which nine batches failed the pH parameter and one batch failed in description and appearance of the solution.

BMSICL issued Show Cause Notices to the firm vide Letter No. 5741 dated 27.09.2024, 6485 dated 18.10.2024, and 9353 dated 10.01.2025. In response, the firm submitted its reply on 03.10.2024; however, upon examination, the reply was found to be unsatisfactory.

The firm stated that it had not received any sample portion from BMSICL for comparison with its control sample, which is a mandatory requirement under Section 18A of the Drugs and Cosmetics Act, 1940, read with sub-section 23(4)(iii). The firm further mentioned that it had checked and tested its control sample—excluding sterility—and found all parameters to be within the specified limits of the Indian Pharmacopoeia (I.P.) 2022. Additionally, the firm noted: "The pH limit is stated as 6.0 to 8.0. However, since this product falls under the Indian Pharmacopoeia (IP), as per the Indian Pharmacopoeia 2022, the correct pH limit is 5.0 to 8.0." The firm also asserted that the standards to be complied with for drugs included in the I.P. are identity, purity, and strength.

In the monograph of I.P., it's mentioned, "Carboxy methylcellulose Eye Drops are a sterile solution of Carboxy methylcellulose Sodium in Purified Water". Also, in I.P Addendum 2024, pH limit is mentioned as 6.0 to 8.0. IP Addendum 2024 refers to the Addendum 2024 to the Indian Pharmacopoeia (IP) 2022. It's an official supplement to the IP 2022 edition.

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) of Drugs & Cosmetics Act 1940 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."*

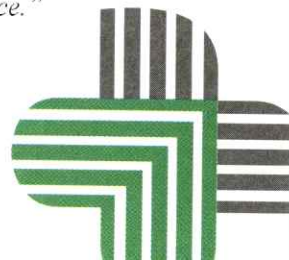
5. Clause 24(f) of the Tender Document is relevant for such cases which reads as follows: *"If the product/sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period"*.

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 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."*

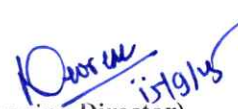
8. Clause 27 B (3) of the Tender Document is relevant for such cases which reads as follows: *"If 3 batches of a particular item supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and /or other parameters, then the particular item of the firm shall 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. As per Clause 27(B) (3) of the Bid document, more than 3 batches (total 10) have been declared as 'Not of Standard Quality' by the BMSICL empanelled Quality Testing Laboratories.

Thus, in light of the provisions contained in the Tender Document and contract agreement, 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, **Carboxy methyl cellulose Eye Drop 0.5% w/v 10ml 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


(Managing Director)

