

File No.:- BMSIC/40030/520-2025/ 3710

Date: -/07/2025

Order

M/s Kanha Biogenetic, situated at Plot No. 1C, EPIP, Phase -I, Jharmajri, Baddi, Distt.- Solan, H.P. has participated in tender reference no. - **BMSIC/DRUGS/25-01** and was shortlisted for financial evaluation based on the recommendation of the Technical Evaluation Committee. Accordingly, the financial bid of the firm M/s Kanha Biogenetic was opened and the firm was found L1 with quoted rate Rs. 0.80/- per Tablet for the drug Albendazole 400 mg Tablet.

Subsequently, a factory inspection of the firm was carried out by a team of Drug Inspectors, as per Clause 15(a) of the Standard Bid Document, which states: *"Inspections of the production and related facilities of bidders/suppliers will be at the discretion of the Tender Inviting Authority. Such inspection may be at any stage before or after acceptance of the Bid or Award of Contract."* The final qualification of the above mentioned firm was subject to report of factory inspection. Information regarding the inspection of the manufacturing premises has also been communicated to firm in advance.

During the inspection, the team observed that the firm has not manufactured the concerned drug, Albendazole 400 mg Tablet, in the past three years. Additionally, the Master Formula Record, Batch Manufacturing Record, and standard testing procedures, as required under Schedule M of the Drugs and Cosmetics Act, 1940, were not produced to the inspecting team. A self-declaration confirming these facts was also submitted by the firm.

Procurement agencies, including BMSICL, require three years of market experience as evidence that a pharmaceutical product has been manufactured & marketed in India for a defined period and comply with regulatory standards. This requirement ensures that the manufacturer is actively producing and selling the product, and that it maintains a good standing in the industry. It serves as a key indicator of the product's quality assurance. Such a requirement plays a vital role in ensuring the credibility, safety, and established use of the drug. It helps verify the product's efficacy and safety, demonstrates market experience, builds procurement confidence, and prevents the supply of unproven or substandard drugs.

The inspection team also identified several other serious concerns regarding the quality and compliance practices of M/s Kanha Biogenetic, as required under Schedule M of the Drugs and Cosmetics Act, 1940, and the rules made thereunder. Drug manufacturing units are required to comply with Schedule M of the Drugs and Cosmetics Act, 1940, which outlines the Good Manufacturing Practices (GMP) and requirements of premises, plant, and equipment for pharmaceutical production. This compliance ensures that the manufacturing processes consistently produce drugs that meet the prescribed quality standards in terms of identity, strength, purity, and safety. Adherence to Schedule M plays a critical role in safeguarding public health by ensuring that only quality-assured medicines reach the market.

Furthermore, it was noted that the said firm had previously been issued a 'Stop Manufacturing' order for Tablets and Capsules (General) by the State Drug Controller-cum-Licensing Authority, Himachal Pradesh. This concerning fact was concealed by the firm M/s Kanha Biogenetic.

BMSICL issued a Show Cause Notice to the firm regarding the aforementioned violations under Clause 3(f), Clause 14(d), Clause 5(k), and Clause 27A of the Standard Bid Document, vide Letter No. 2708 dated 18.06.2025. The firm was directed to submit a written reply to the Show Cause Notice within



seven (07) days from the date of receipt of the said letter. The reply, submitted vide Letter No. KB/25-26/004 dated 24.06.2025, was duly received; however, upon examination, it was found to be unsatisfactory.

During the course of factory inspection, the firm failed to produce critical manufacturing documents such as the Master Formula Record (MFR), Batch Manufacturing Record (BMR), and Standard Testing Procedures (STP). These documents are essential for assessing a firm's compliance with Good Manufacturing Practices (GMP), quality assurance protocols, and overall operational capability. They are expected to be readily available during regulatory inspections. The non-availability of these documents at the time of inspection constitutes a serious non-compliance.

The MFR and BMR are vital records that demonstrate adherence to approved and standardized production procedures, while the STP confirms the implementation of quality control measures necessary to maintain product safety and efficacy. The failure to produce these documents during inspection undermines the credibility of the firm's manufacturing and documentation practices. Although the documents were submitted later, this was only after issuance of a show-cause notice, and thus amounts to a reactive measure that does not remedy the original non-compliance at the time of inspection. This delay raises concerns of potential backdating or retrospective data preparation, which is strictly prohibited under GMP.

Additionally, the firm's explanation regarding the mistaken signing of a self-declaration during the audit is not credible. The firm claimed that due to the audit team's sudden departure, certain documents requiring signatures were inadvertently signed, including a self-declaration. However, the self-declaration in question was prepared and submitted voluntarily by the firm, on its official letterhead, bearing an authorized signature and official seal. It explicitly states that the firm had not manufactured the specified product in the last three years. This document was not created or imposed by the audit team. Therefore, the claim that it was signed by mistake under audit pressure is unfounded and lacks merit.

Furthermore, the firm referenced a revocation order (vide letter no. HFW-H (Drugs) 04/16-5855 dated 07.08.2024), issued by the State Drugs Controller-cum-Licensing Authority, Himachal Pradesh, Baddi, District Solan. This revocation order was issued after a joint inspection conducted by officials from the State Licensing Authority and the CDSCO from 30.10.2023 to 01.11.2023. The second joint inspection on 30.07.2024 found that corrective actions had been taken, leading to the revocation of the stop-manufacturing order on 07.08.2024. This confirms that a 'Stop Manufacturing' order for Tablets and Capsules (General) had indeed been issued earlier. This concerning fact was concealed by the firm, M/s Kanha Biogenetic.

The issuance of a "Stop Manufacturing" order, along with the firm's failure to produce critical manufacturing documents such as the Master Formula Record (MFR), Batch Manufacturing Record (BMR), and Standard Testing Procedures (STP) during the factory inspection, constitutes a significant regulatory concern. These failures demonstrate the firm's non-compliance with Good Manufacturing Practices (GMP), quality assurance protocols, and overall operational deficiencies that directly affect its manufacturing capabilities. This regulatory action was in effect within the last three years, a fact that the firm failed to disclose at the time of bid submission, and further compounded by its inability to produce essential documents during the factory inspection. This behavior amounts to a violation of the obligations under the tender conditions and reflects a withholding of critical information relevant to the integrity of the bidding process. Such omission represents a clear violation of Clause 14(d) of the Standard Bid Document, which expressly requires disclosure of any suspension, cancellation, or non-renewal of a



manufacturing license. The deliberate non-disclosure of this significant regulatory action directly impacts the firm's eligibility to participate in public procurement processes.

As per Clause 5(k) of Bid Document, "An Affidavit (with stamp) regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV."

Annexure IV, Point No. 3 of the bid document states that: "The information / documents furnished along with the above application are true and authentic to the best of my knowledge and belief. I / we, am / are well aware of the fact that furnishing of any false information / fabricated document would lead to rejection of my tender at any stage besides liabilities towards prosecution under appropriate law."

As per Clause 14(d) of Bid Document, "If at any stage, it is found that the tender has been successfully obtained by the bidder by submitting forged/fabricated certificates/documents/licenses and/or by concealing the fact about blacklisting/debarring/de-registration of the firm by Govt. of India/Suspension/Cancellation/non-renewal of the manufacturing license of the bidder firm, the tender bid/rate contract may be rejected/terminated and suitable punitive action may be taken against the firm"

As per Clause 27 A of the bid document, "If the Tenderer fails to execute the agreement / to deposit performance security / to perform the obligations under the tender conditions / commits default in the performance of the contract/agreement, such Tenderers will be blacklisted for a period of 2 years by BMSICL from the date of intimation besides forfeiture of EMD/Performance Guarantee. The Tenderers who have withdrawn after participating in the tender either fully or partially, the entire firm/company will be blacklisted for a period of 2 years from the date of intimation by BMSICL apart from forfeiture of the Security Deposit/EMD."

Thus in light of the provisions contained in the tender document, the firm, **M/s Kanha Biogenetic**, situated at Plot No. 1C, EPIP, Phase -I, Jharmajri, Baddi, Distt.- Solan, H.P. is hereby blacklisted for a period of two (02) years from the date of issue of this order apart from forfeiture of security deposit/EMD.


(Managing Director)

Memo No. - BMSIC/40030/520-2025/ 3710

Date- 10 /07/2025

Copy to: The Managing Director, M/s Kanha Biogenetic, for information and action.


(Managing Director)

Memo No.- BMSIC/40030/520-2025/ 3710

Date- 10 /07/2025

Copy to:

1. The Additional Chief Secretary, Department of Health, Govt. of Bihar for kind information please.
2. Executive Director, State Health Society, Bihar for kind information please.
3. The CGM (Supply Chain), General Manager (Logistics), General Manager (Finance), BMSIC for information and necessary action. GM (Logistics) is requested to ensure publication of this order on the official website of BMSICL and Notice Board as well.
4. MD, All Medical Corporations and Procurement Agencies all over India for information and necessary action please.
5. CEO, Government e- Marketplace for information and necessary action please.
6. All Civil Surgeons, Bihar and Superintendents of all Govt. medical colleges and hospitals of Bihar for information and necessary action.


(Managing Director)

