

JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD.

(Public Sector Undertaking of Govt of Jammu & Kashmir)

Corporate Head Office: Plot N-58 Friends Colony, Satyam Road-Marble Market, Trikuta Nagar Jammu.
Corporate Office Kashmir: Opposite, State Motor Garage Deptt. Baramulla National Highway, Bemina
Telephone: 0191-2478842, 0191-2476548 (Jammu).

JKMSCL

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Subject:- Debarring/ Blacklisting of product manufacture by M/s Jackson Laboratories Pvt. Ltd.

Order No: **51** of 2021

Dated : **05-02-2021**

Whereas, the Medicines i.e B-Complex Tablets NFI bearing batch No.T-17313 and T-17377 manufactured by M/s Jackson Laboratories Pvt. Ltd 22-24, Majitha Road, Bypass, Amritsar-143001(India), were supplied to Jammu and Kashmir Medical Supplies Corporation Ltd. against the Annual Rate Contract approved by J&K medical Supplies Corporation Ltd. for the **Tender No; JKMSCL/Tend/Drug & Med/05/2017, dated 02-02-2017.**

Whereas, both the batches T-17313 & T-17377 were sent by Quality Control Cell, JKMSCL for quality control check to Empanelled Laboratory of JKMSCL i.e. M/s Oasis Test House and the report of the drug in discussion was received on 04-12-2018 wherein both the batches were declared as "**NOT STANDARD QUALITY**" vide report No; EHL/2019-R180928036 dated 03-12-2018 and R181024012 dated 03-12-2018 respectively for the reasons that both the batches fails in "Assay of D-Pantothenate".

Whereas, vide this office letter No. JKMSCL/QC/J/2018/1269-74 dated. 04-12-2018 issued by Medical Officer (QC), the said firm was asked to explain its position with regard to the declaration of said medicine as NSQ within three days, however no reply was received from the said firm.

Whereas 2nd portion of both the batches of the drug in discussion were sent to another empanelled laboratory. of JKMSCL i.e. Inter Testing Centre Pvt.

Ltd for retesting/cross checking vide Medical Officer, Quality Control Jammu No: JKMSCL/QC/J/2018/1160, 13-10-2018.

Whereas analytical report of Batch T-17313 of drug in discussion was received on 25-12-2018, wherein the said batch(T-17313) of drug was declared as "**STANDARD QUALITY**" vide report No: PO1-1810220136 Dated 25-10-2018.

However, batch No: T-17377 with test report No: R181024012 dated 03-12-2018 was declared as "**NOT OF STANDARD QUALITY**" for the reason that sample fails in "**Assay of D-Pantothenate**".

Whereas Controller, Drug and Food Control Organization vide MO(QC) letter No: JKMSCL/QC/J/2018/1275-80, 04-12-2018 & reminder No: JKMSCL/QC/J/2019/28-34, 23-01-2019 was requested to draw additional sample of the drug B-Complex NFI with batch No: T-17313 & T-17377 for testing from Regional Drug Ware House, Anantnag and Rajouri.

Whereas both the batches of drug in question were lifted by Drug Inspector, Rajouri, J&K for the purpose of test analysis and both the batches were declared as '**NOT OF STANDARD QUALITY**' by the Govt. Analyst Regional Drugs Testing Laboratory, Chandigarh vide test report No; LSD/RDTL/1702/18-19, dated 26-4-2019 and LSD/RDTL/1703/18-19 dated 26-04-2019 respectively.

Whereas both the batches of the drugs were sent to, the Director, Central Drugs Laboratory for retesting under section 25(4) of Drugs & Cosmetics Act, 1940 through Munsif Judicial Magistrate 1st Class, Kotranka Jammu.

Whereas the test report from Director In-charge, Central Drugs Laboratory Calcutta of both the batches (T-17313 & T-17377) of the said drug was received on 08-07-2020 wherein both the batches were declared as '**NOT OF STANDARD QUALITY**' vide report No; 2-1/2020/SS/CC-02/66 dated 19-6-2020, and 2-1/2020-SS/CC-03/65 dated 19-6-2020 respectively for the reason

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that Batch No T-17313 does not conform to claim with respect to the test for "Identification " of Calcium D-Pantothenate and "Assay " of Vitamin B1 & Calcium D-Pantothenate and the batch No T-17377 does not conform to claim with respect to the test for "Identification" of calcium D-Pantothenate and "Assay of Vitamin B1, Vitamin B6 & Calcium D-Pantothenate. **The test report from Central Drugs laboratory is conclusive evidence of the fact under section 25(4) of Drugs and Cosmetic Act -1940.**

Whereas, vide this officer order No. 108-JKMSCL of 2020 Dated 02-09-2020 a team comprising of following officers was constituted to inquire into the quality failure of two (02) batches of the drugs.

1. General Manager (Adm)
2. General Manager (P&S).
3. In-charge Quality Control, JKMSCL,
4. Senior Law Officer, JKMSCL.
5. Medical Officer , Quality Control, JKMSCL.

Whereas, the enquiry team submitted its report/opinion with the following recommendations:-

As per the policy for Blacklisting/ Debarring of Product or Company under clause-4 read with sub-clause-4.5

"If two batches of a particular item supplied under a tender tenure by the supplier are declared as Not of Standard Quality by an empanelled lab or Govt. Lab in grossly substandard and such failures are further confirmed by another empanelled lab/Govt. Lab then the particular item of the drug shall be liable for blacklisting for a period of not less than 2(two) years.

The action as per "Policy for Blacklisting/Debarring of Product or Company" under clause-4, on account of Quality failure of Drugs and Medicines" read with sub-clause 4.5 may be taken against the manufacturer i.e. M/s Jackson Laboratories Pvt. Ltd., 22-24, Majitha Road Bypass, Amritsar, India-143001.

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Whereas, the matter was examined in light of above quality testing report and recommendation of the enquiry team, the competent authority has decided to take necessary action in the matter in terms of para 4.5 of Procedures and policies/Guidelines (book) regarding Policy for blacklisting/debarring of product of company.

Therefore, in view of the above stated facts of this case and relevant policy guidelines/conditions of Purchase Orders and NIT, it is hereby ordered that the **Product B-Complex Tablets NFI manufactured by M/s Jackson Laboratories Pvt. Ltd 22-24, Majitha Road, Bypass, Amritsar-143001(India)**, is hereby debarred/blacklisted from JKMSCL for 02(Two) years from the date of issuance of this order.


Sd/-
Managing Director
J&K Medical Supplies Corporation Ltd.

No. JKMSCL/Adm//BL/2020/34/6454-61

Dated: 5-02-2021

Copy to the:

1. Financial Commissioner to Government, Health and Medical Education Department, Civil Secretariat, Jammu.
2. Financial Advisor/Chief Account Officer, JK, Medical Supplies Corporation Ltd.
3. General Manager-K, J&K Medical Supplies Corporation Ltd.
4. In-charge Quality Control Cell, J&K Medical Supplies Corporation Ltd.
5. Incharge Medical Officers Drug Ware Houses _____
6. Incharge IT cell for uploading the same on the official site.
7. PA to Managing Director, J&K Medical Supplies Corporation Ltd.
8. M/s Jackson Laboratories Pvt. Ltd 22-24, Majitha Road, Bypass, Amritsar-143001(India).


Dy. General Manager (Adm)
J&K Medical Supplies Corp. Ltd