



JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD

(Public Sector Undertaking of Govt of Jammu & Kashmir)

Corporate Head Office: Plot No: 58, Friends Colony, Satyam Road, Trikuta Nagar Jammu

Corporate Office: Opp State Motor Garages Near Haj House, Bemina, Srinagar

Telephone: 0191-2580842, Fax: 0191-2581845 (Jammu); Telefax: 0194-2432008 (Srinagar)

Email: mdjkmssl2@gmail.com, personalsectionmd@gmail.com

Sub:- Inj. Enoxaparin Sodium 60 mg / 0.6 ml manufactured by M/s Samarth Life Sciences (P) Ltd. Supplied by M/s Saimvd Medicals (P) Ltd- declared as not of standard quality- Blacklisting of Product – Order issued...regd.

ORDER: 57 of 2023
DATED: 04-7-2023

Whereas; three Batches of Inj. Enoxaparin Sodium 60mg/0.6ml were declared as 'Not of Standard Quality' (NSQ) by CDSCO & NIB, Noida manufactured by M/s Samarth Life Sciences (P) Ltd. supplied by M/s Saimvd Medicals (P) Ltd.

Whereas; the following batches of Inj. Enoxaparin Sodium 60mg/0.6ml, Drug Code (370A) were declared as 'Not of Standard Quality' (NSQ) by Central Drugs Standard Control Organization (CDSCO) & National Institute of Biologicals, Noida (NIB):

Batch No.	Report No.	Report Dated	Testing Agency
SENXB2118	32-20/2022-SS/DCA(J)-1/376	11-May-22	CDSCO (CDL KOLKATA)
SENXB2211	EHL/2022-23/ENP/02	16-Feb-23	NIB (National Institute of Biologicals, Noida)
SENXB2210	EHL/2022-23/ENP/03	24-Feb-23	

Whereas; subsequent to the reports of three batches which were declared as NSQ by CDL Kolkata & NIB, representations were received from the firm stating that they have approached NIB with the request to permit re-testing of the said samples. It was also conveyed by the firm that NIB has denied their request for the re-testing.

Whereas; Clause 4.6 of policy for Blacklisting / Debarring of Product or Company of JKMSCL states that,

"If three batches of a particular item supplied under a tender tenure by the supplier are declared as Not of Standard Quality (NSQ) during its entire shelf life by an empaneled lab or Govt. Lab in test for assay and / or in any other parameter(s) and if such failures are further confirmed by another empaneled lab or Govt. Lab during its entire shelf life, the particular item of the drug shall be liable for blacklisting for a period of not Less than 2 years."

Whereas; Clause 5.8 of policy for Blacklisting / Debarring of Product or Company of JKMSCL states that,

"If the sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final unless challenged as per provisions of Drugs & Cosmetics Act, 1940."

Whereas; in this context a meeting was held in the chamber of Controller D&FCO on 24/05/23 and clarification was sought from the office of the Controller, Drug & Food Control Organization of J&K in view of the representation submitted by the firm viz M/s Samarth Life Sciences (P) Ltd. The clarification was provided by Controller D&FCO vide Letter NO- DFO/D-713/746 dated 25/05/23, an extract of which is reproduced hereunder: -

- *"Enoxaparin sodium Injection IP B.No. SENXB2118 D/M: 12/2021 E/D:11/2023 Mfd. by Samarth Life Sciences (P) Ltd. has been declared not of standard quality by Govt. Analyst, Central Drugs Laboratory, Kolkata vide its report No. 32-20/2022-SS/DCA(J)-1/376 dated:11.05.2022.*
- *The manufacturer has a right to adduce its evidence in contravention to the report of Government Analyst subject to the conditions laid down under section 25(3) of the Drugs & Cosmetics Act, 1940 which is reproduced as under:*
- *As per Section 25(3) in the drugs and Cosmetics Act, 1940 Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken [or the person whose name, address and other particulars have been disclosed under section 18A] has, **within twenty-eight days of the receipt of a copy of the report**, notified in writing the inspector or the court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report.*
- *It may not be out of place to mention that Enoxaparin injection is official in Indian Pharmacopeia (Monograph) and as such the Government Analyst /Analytical chemist is not under obligation to obtain method of analysis from the manufacturer."*

Whereas; a meeting of disciplinary committee was held on 26th May 2023 wherein it was decided that a show cause notice (SCN) be issued to the firm in lieu of principles of natural justice before initiating action against the firm as per clause 4.6 of policy for Blacklisting / Debarring of Product or Company of JKMSCL.



Whereas; the firm approached JKMSCL for granting of extension to file the reply of show cause notice and in lieu of the same an extension was granted to the firm to file its reply by or before 20.06.2023. Accordingly, the firm furnished its reply on 20.06.2023, the contents of which were examined in detail & were not found satisfactory and justifiable.

Whereas; it is pertinent to mention here that another batch of the same product viz Inj. Enoxaparin Sodium 60mg/0.6ml has been declared as 'Not of Standard Quality' (NSQ) by NIB, Noida manufactured by M/s Samarth Life Sciences (P) Ltd. supplied by M/s Saimvd Medicals (P) Ltd. **(Batch No SENXB2212 vide Report No. EHL/2023-24/ENP/02 dated:08-06-23).** As such, as on date four batches of the subject drug have been declared as NSQ by CDL/NIB.

Whereas; Section 25(4) of Drugs & Cosmetics Act, 1940 clearly states that,

"Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the Magistrate under subsection (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein".

Whereas; it has been observed that all the batches in question of the said drug have been tested either by Central Drug Laboratory or NIB, the reports of which are conclusive and in agreement with section 6 of Drugs & Cosmetics Act, 1945.

Whereas; manufacturing and supplying of **"Not of Standard Quality"** drug is an offence under section 18(a) (i) of the Drug & Cosmetics Act, 1940. Such drugs can endanger the lives of patients; it is the responsibility of manufacturer to supply quality drugs meeting out all the prescribed parameters of quality.

In lieu of the aforementioned facts and in consonance with Clause 4.6 and Clause 5.8 of policy for Blacklisting / Debarring of Product or Company of JKMSCL, it is hereby ordered that item Inj. Enoxaparin Sodium 60mg/0.6ml manufactured by M/s Samarth Life Sciences (P) Ltd. supplied by M/s Saimvd Medicals (P) Ltd is blacklisted in JKMSCL for a period of 02 years from the date of issuance of this order and bid security / EMD of the firm for the connected NIT is forfeited.

Further, firm is also directed to lift back the supplies, if any from RDWHs of JKMSCL immediately on its own cost.



This order is without prejudice to legal & criminal action to be taken, if any, by JKMSCL in the matter.


 (Pankaj Gupta), JKAS
 Managing Director
 J&K Medical Supplies Corporation Ltd
 03/7/2023
 Dated: 04/7/2023

No: JKMSCL/PS/MD/2023-24/ 486-95

Copy for information to the:

1. Administrative Secretary, Health and Medical Education Department, J&K, Jammu.
2. State Drug Controller, Drugs & Food Control Organization, J&K.
3. Managing Directors of RMSCL, TNMC, KMSCL, UPMSCl, MPHSCl, GMSCL, PHSC and other Medical Corporations.
4. Financial Advisor / CAO, JKMSCL to ensure that no payment on this account is disbursed to the said firm.
5. General Manager (P&S) / (Adm), JKMSCL.
6. Assistant Director, Quality Cell, JKMSCL.
7. Medical Officer, Quality Control, JKMSCL.
8. All Drug Ware Houses of JKMSCL.
9. Assistant Programmer (M), for uploading the same on the website
10. M/s Samarth Life Sciences (P) Ltd, Mumbai.
11. Office Copy.