

**Subject: Debarred / Blacklisting order in favour of M/s Samarth Life Sciences Pvt. Ltd., Samarth House, 168, Bangur Nagar Off Link Road, Near Ayappa Temple Goregaon (W), Mumbai-40090.**

**ORDER NO: 122-JKMSCL of 2025**

**DATED: 14 /01/2025**

Whereas, the NIT for procurement of various Disinfectants and Drugs was issued vide No. JKMSCL/Med/2022/564 dated 23-12-2022, wherein the item Inj. Enoxaparin Sodium 40mg/0.4ml, per prefilled syringe was also tendered. After following due procedure, the Rate Contract for the item Inj. Enoxaparin Sodium 40mg/0.4ml, per prefilled syringe was awarded for a period of 02 years to M/s Samarth Life Sciences Pvt. Ltd., Samarth House, 168, Bangur Nagar Off Link Road, Near Ayappa Temple Goregaon (W), Mumbai-40090 vide no. JKMSCL/GM(Drugs)/564/16742-48 dated 22-12-2023.

Whereas, the Purchase Orders were placed in favour of the firm for the subjected item and the samples were sent by Quality Control Section of JKMSCL for quality testing to National Institute of Biologicals, Laboratory.

Whereas, the following three batches of subjected item were declared as "Not of Standard Quality" and the firm was informed vide letters mentioned below against each batch:

| S. No. | Name of Item   | Batch No.  | Report No. & Date  | Communication issued to firm                    |
|--------|--|------------|--|---|
| 1.     | Inj. Enoxaparin Sodium 40mg/0.4ml, per prefilled syringe | SENXA2422A | EHL/2024-25/ENP/07<br>D.O.M: 05/24<br>D.O.E: 04/26<br>23-09-2024 | JKMSCL/QC/J/ 2024-25/2676-84 dated 26-09-2024   |
| 2.     |  | SENXA2423A | EHL/2024-25/ENP/08<br>D.O.M: 05/24<br>D.O.E: 04/26<br>26-09-2024 | JKMSCL/QC/J/ 2024-25/2882-91 dated 14-10-2024   |
| 3.     |  | SENXA2424A | EHL/2024-25/ENP/09<br>D.O.M: 06/24<br>D.O.E: 05/26<br>26-09-2024 | JKMSCL/QC/J/ 2024-25/2892-2901 dated 14-10-2024 |

Whereas, the Clause(s) 4.6 & 5.8 of Policy for Blacklisting /Debarring of Product / Company are re-produced as under:

*Clause 4.6: If three batches of a particular item supplied under a tender tenure by the supplier are declared as Not of Standard Quality during its entire shelf life by an empanelled lab or Govt. Lab in test for assay and / or in any other parameter(s) and if such failures are further confirmed by another empanelled 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.*

*Clause 5.8: In case when the second report is contradictory to the first report, the statutory sample will be sent to Govt. Lab, whose report shall be final and 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, the matter was placed before the Disciplinary Committee in its meeting held on 25-10-2024 and it was unanimously decided by the Committee that in view of principles of natural justice before initiating action against the firm, a Show Cause Notice be issued to the firm to seek clarification in the matter and also give reason that why JKMSCL shall not initiate the process of blacklisting.

Whereas, a Show Cause Notice was issued vide no. JKMSCL/Adm/2024/6664-68 dated 06-11-2024, wherein the directions were issued to the firm to explain the position regarding the above mentioned facts within 05 days.

Whereas, in response to the Show Cause Notice, the firm made submission to extend the time for submission of explanation and also requested for personal hearing.

Whereas, on 05-12-2024 the firm made various submissions through e-mail and copy of the same was placed before the Disciplinary Committee meeting held on 07-01-2025 and it was decided that a notice be issued to M/s Samarth Life Sciences Pvt. Ltd. with the directions to submit current status on the matter as well as with regard to adduce evidence in contravention to the test report made as per Drugs & Cosmetics Act 1940, if any, be communicated to JKMSCL within 3 days positively.

Whereas, vide this office communication No. JKMSCL/DISC/2024-25/10012-17 dated 07-01-2025, the firm was directed to submit current status on the matter as well as with regard to adduce evidence in contravention to the test report made in light of Drug & Cosmetic Act 1940, if any, within 3 days positively and the firm submitted its reply on 9<sup>th</sup> January 2025.

Whereas, the matter was again placed before the Disciplinary Committee in its meeting held on 14-01-2025 for further discussion and the Committee made following observations:

- 14.1.25
- i) That the instances quoted by M/s Samarth Life Sciences Pvt. Ltd., in respect of RMSCL ( point 3.A.) and the documents there of, do not correspond with the case under purview in JKMSCL since the case of RMSCL pertains to only single batch of the item declared as NSQ in contrast to the instant case of JKMSCL wherein 03 batches of the subject item have been declared as NSQ on the parameters of assay and/or sterility by NIB [National Institute of Biologicals] which is an apical premier Institute of GOI.
  - ii) As far as suggested validation by CDL Kolkata of the product Streptokinase 15 lakh IU is concerned, the facts on account of the documents of the previous two tests conducted by NIB reveal that the results of the two reports by NIB were contradictory; whereupon the test had to be undertaken for the third time for conclusive result from an equivalent &/or a higher laboratory i.e CDL Kolkata under rules.

- iii) That the analogy drawn by the firm, by citing the aforesaid cases, does not correspond to the facts applicable in case of the batches supplied to the JKMSCL and declared NSQ by NIB. Hence the similar intervention is not feasible under rules. That the firm instead of following up the requisite legal procedure under rules, is instead requesting for the exemptions which are not applicable as per the SPP and the Quality Control Manual of JKMSCL.

Whereas, in lieu of the aforementioned facts and in consonance with the clauses 4.6 and 5.8 the committee recommended to blacklist / debar the item Inj. Enoxaparin Sodium 40mg/0.4ml, per prefilled syringe manufactured by M/s Samarth Life Sciences (P) Ltd for a period of 02 years and the bid security/EMD of the firm for the connected NIT be forfeited. Further, firm may also be directed to lift back the supplies, if any, from the RDWHs of JKMSCL immediately at its own cost.

Therefore, in light of all the above mentioned facts, M/s Samarth Life Sciences Pvt. Ltd., Samarth House, 168, Bangur Nagar Off Link Road, Near Ayappa Temple Goregaon (W), Mumbai-40090 is hereby blacklisted / debarred from JKMSCL for the item Inj. Enoxaparin Sodium 40mg/0.4ml for the period of 02 years from the date of issuance of this order. It is further ordered that the EMD submitted by the firm against the above mentioned NIT is also forfeited forthwith.

**Issued with the approval of TIA.**


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

No: JKMSCL/DISC/2024-25/120013-24,

Dated: 14/01/2025

Copy for information to the:

1. Secretary to Government, Health & Medical Education Department, Civil Secretariat, Jammu / Srinagar.
2. All Principals, Govt. Medical Colleges, J&K / Director Health Services, Jammu / Kashmir.
3. State Drug Controller, Drug & Food Control Organization, J&K.
4. Financial Advisor/CAO, J&K Medical Supplies Corporation Ltd.
5. General Manager (K), J&K Medical Supplies Corporation Ltd.
6. Dy. General Manager (P&S), J&K Medical Supplies Corporation Ltd.
7. Dy. General Manager (Legal), J&K Medical Supplies Corporation Ltd.
8. Medical Officer (QC), J&K Medical Supplies Corporation Ltd.
9. Assistant Legal Remembrancer, J&K Medical Supplies Corporation Ltd.
10. PA to Managing Director, J&K Medical Supplies Corporation Ltd.
11. All Medical Supplies Coporation(s) Ltd.
12. M/s Samarth Life Sciences Pvt. Ltd., Samarth House, 168, Bangur Nagar Off Link Road, Near Ayappa Temple Goregaon (W), Mumbai-40090.
13. Office Copy

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