



JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD

(Public Sector Undertaking of Govt of Jammu & Kashmir)

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Sub:- Injection Compound Sodium Lactate 500 ml (Ringer Lactate) manufactured and supplied by M/s Pharma Impex Laboratories (P) Ltd - declared as not of standard quality- Blacklisting of Product - Order issued...regd.

ORDER: 08 of 2023

DATED: 04 - 7 - 2023

Whereas; adverse drug reactions were reported by various institutions of UT of J&K with respect to various batches of injection Compound Sodium Lactate 500ml (Ringer Lactate) manufactured & provided by M/s Pharma Impex Laboratories (P) Ltd, West Bengal to JKMSCL.

Whereas; stop use notice was issued by JKMSCL and all the batches were recalled back. Subsequently, vide letter No: JKMSCL/GM/P&S/2021/8042-48, dated 28-10-2021 & letter No: MD/PS/JKMSCL/2021-22/1860-62, dated 15-11-2021, M/s Pharma Impex Laboratories (P) Ltd, West Bengal was asked to lift back the supplies.

Whereas; the Rate Contract for the subject item was cancelled vide letter No: JKMSCL/GM(Drugs)/NIT-402/2021/0205-09, dated 24-12-2021 and the matter was reported to ADRM cell (under Pharma Co-vigilance programme of India) and the State Drug Controller, Drug & Food Control Organisation J&K.

Whereas; JKMSCL received the reports of testing from State Drug Analyst, Drug & Food Control Organisation J&K wherein eleven (11) batches were declared as 'Not of Standard Quality' as the batches failed on the Sterility Parameters.

Whereas; the matter was placed before the disciplinary committee on dated 06-05-2022 at Corporate Head Office, Trikuta Nagar Jammu and showcause notice was served to the manufacturer.

Whereas; a letter no Nil dated 28-12-2021 and email dated 15-02-2022 was received from M/s Pharma Impex Laboratories (P) Ltd, West Bengal in which it was stated that:

"we wish to adduce evidence in contravention of the Govt. Analyst report under section 25(3) under Drugs and Cosmetic Act 1940".

Whereas; a meeting was held in the Office Chamber of the Controller D&FCO on 24-05-2023 in which the opinion of the Controller was sought in the matter. The status of the samples of the Compound Sodium Lactate manufactured by M/s Pharma Impex Laboratories (P) Ltd, West Bengal sent for retesting to the appellate laboratory (Central Drugs Laboratory Kolkata) through Chief Judicial Magistrate, Court of Chief Judicial Magistrate (Jammu, Srinagar & Kathua) was provided by the Controller Drugs & Food Control Organisation J&K wherein it was intimated that 05 batches have been declared as 'Not of Standard Quality' (NSQ) by the appellate Laboratory, Central Drugs Laboratory Kolkata with details hereunder:-

S. No	Name of the Drug	Name of the Manufacturer	Sample lifted by	Batch No.	Test Report No. & Date	Reason for declaring the drug as not of standard quality	Current Status
1.	Compound Sodium Lactate Injection I.P RL (JKMSCL Hospital Supply 2021-22)	Pharma Impex Laboratories Pvt. Ltd. South Uttarbagg, Ramnagar, Baruipur, Distt. South, 24PGS West Bengal, 743387 India	Zone IV Srinagar	2105B0325 M/D:06/2021 E/D: 05/2024	L/DA/2021-22/1626 Dated:- 25-01-2022	The sample does not comply to I.P requirement w.r.t the test for sterility	Sample declared not of standard by the appellate Laboratory i.e CDL Kolkata vide report No. 2-1/2022-SS/CC-274/824 dt 13-01-2023
2.	Compound Sodium Lactate Injection I.P RL (JKMSCL Hospital Supply 2021-22)	Pharma Impex Laboratories Pvt. Ltd. South Uttarbagg, Ramnagar, Baruipur, Distt. South, 24PGS West Bengal, 743387, India	Zone IV Srinagar	2105B0323 M/D :06/2021 E/D: 05/2024	L/DA/2021-22/1627 Dated:- 25-01-2022	The sample does not comply to I.P requirement w.r.t the test for sterility	Sample declared not of standard by the appellate Laboratory i.e CDL Kolkata vide report No. 2-1/2022-SS/CC-273/788 dt 03-01-2023
3.	Compound Sodium Lactate Injection I.P RL (JKMSCL Hospital Supply 2021-22)	Pharma Impex Laboratories Pvt. Ltd. South Uttarbagg, Ramnagar, Baruipur, Distt. South, 24PGS West Bengal, 743387 India	Zone IV Srinagar	2105B0329 M/D :06/2021 E/D: 05/2024	L/DA/2021-22/1628 Dated:- 25-01-2022	The sample does not comply to I.P requirement w.r.t the test for sterility	Sample declared not of standard by the appellate Laboratory i.e CDL Kolkata vide report No. 2-1/2022-SS/CC-275/791 dt 03-01-2023
4.	Compound Sodium Lactate Injection IP (JKMSCL Hospital Supply)	Pharma Impex Laboratories Pvt. Ltd. South Uttarbagg, Ramnagar, Baruipur, Distt. South, 24PGS West Bengal, 743387 India	DCO Zone V Srinagar	2105B0326 M/D :06/2021 E/D: 05/2024	L/DA/2022-23/231 Dated:- 27-04-2022	The sample does not comply to the test for Sterility.	Sample declared not of standard by the appellate Laboratory i.e CDL Kolkata vide report No. 2-1/2022-SS/CC-250/699 dt 09-12-2022
5.	Compound Sodium Lactate	Pharma Impex Laboratories Pvt. Ltd. South	Zone V Srinagar	2105B0334 M/D :06/2021 E/D: 05/2024	L/DA/2022-23/307 Dated:-	The sample does not comply to the	Sample declared not of standard by the appellate

	Injection LP (JKMSCL Hospital Supply)	Uttarbag, Ramnagar, Baruipur, Distt. South, 24PGS West Bengal, 743387 India			18-05-2022	test for Sterility	Laboratory i.e CDL Kolkata vide report No. 2-1/2022- SS/CC-153/488 dt 29-09-2022
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Whereas; as per clause 4.6 of policy for Blacklisting / Debarring of Product or Company of JKMSCL;

'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; the matter was again placed before disciplinary committee and it was unanimously recommended that the firm M/S Pharma Impex Laboratories (P) Ltd. be blacklisted for the item Compound Sodium Lactate Injection IP IV 500ml (Ringer Lactate) for the period of 02 years from the date of issuance of the order.

Whereas; in consonance with the principles of natural justice a Showcause Notice was issued to the firm viz. M/S Pharma Impex Laboratories (P) Ltd on 14-06-2023 wherein firm was directed to explain the position within 02 working days. However, the dates for submission of replies of the Showcause Notice was extended upto 20-06-2023 in lieu of the request submitted by the firm on 16.06.2023.

Whereas; a reply was received from the firm on 20.06.2023 which was not found satisfactory and justifiable by JKMSCL. The firm requested JKMSCL to furnish the copies of test report in form no. 2 received from CDL, Kolkata. The firm may approach Office of Controller, D&FCO for the same.

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, it is hereby ordered that the item "Compound Sodium Lactate Injection IP IV 500ml (Ringer Lactate) manufactured by M/S Pharma Impex Laboratories (P) Ltd is blacklisted in JKMSCL for a period of 02 years from the date of issuance of this order in consonance with the clause 4.6 of Policy of Blacklisting/Debarring of product or company of JKMSCL 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

No: JKMSCL/PS/MD/2023-24/496-505

Dated: 04/07/2023

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, UPMSC, MPHSC, 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 Pharma Impex Laboratories (P) Ltd, Kolkata.
11. Office Copy.