



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

(Assuring Quality, Saving lives)

Phone No.:

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OSMCL-QA-MISC-0031-2022 Letter No. 8079/ OSMCL/QA/I-010/2022

Date. 21.10.2022

ORDER

Ms. SWAROOP PHARMACEUTICALS PVT. LTD., A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001 was placed with orders to supply I.V. Compound Sodium Lactate (Ringers Lactate) RL 500ml bottle vide Purchase Order No. CR24694 Dtd. 22.11.2021, CR25345 Dtd. 01.02.2022 and CR24071 Dtd. 15.09.2021. The firm supplied the drug in number of batches, out of which five (05) number of batches have been declared as "Not of Standard Quality" by the Govt. Analyst CDL, Kolkata, which have been communicated to the supplier with enclosed copies of test reports vide this office letter no. 5499 Dtd. 30/07/2022, 6301 Dtd. 02/09/2022, 6304 Dtd. 02/09/2022 and 3902 Dtd. 07/06/2022 under intimation to the Drugs Licensing & Controlling Authority, Office of the commissioner, Food Safety & Drug Administration (U.P), Sector-C, Aliganj, Lucknow (U.P), India. The details of batches of the subject drug and the reason for declaring the said batches as NSQ are mentioned below;

Sl. No.	Batch No.	Mfg. Dt.	Exp. Dt.	Ref. PO. No. & Date	Status	Reason for declaring NSQ	Mfd. By
1.	S2FBV18	Feb-2022	Jan-2024	CR24694 Dt. 22.11.2021	NSQ	'Sterility' vide test report no. 17-2/2022-SS/OR-07/959.	Ms. SWAROOP PHARMACEUTICALS PVT. LTD. A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001
2.	S2FBV24	Feb-2022	Jan-2024	CR24694 Dt. 22.11.2021 and CR25345 Dt. 01.02.2022	NSQ	'Bacterial Endotoxins' and 'Sterility' vide test report no. 17-2/2022-SS/OR-016/1497.	Ms. SWAROOP PHARMACEUTICALS PVT. LTD. A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001
3.	S2FBV27	Feb-2022	Jan-2024	CR25345 Dt. 01.02.2022	NSQ	'Bacterial Endotoxins' vide test report no. 17-2/2022-SS/OR-012/1208.	Ms. SWAROOP PHARMACEUTICALS PVT. LTD. A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001
4.	S2FBV33	Feb-2022	Jan-2024	CR24694 Dt. 22.11.2021	NSQ	'Bacterial Endotoxins' vide test report no. 17-2/2022-SS/OR-17/1302	Ms. SWAROOP PHARMACEUTICALS PVT. LTD. A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001
5.	S2FBZ325	Nov-2021	Oct-2023	CR24071 Dt. 15.09.2021	NSQ	'Bacterial Endotoxins' and 'Sterility', vide test report no. 17-2/2022-SS/OR-06/517.	Ms. SWAROOP PHARMACEUTICALS PVT. LTD. A-10, Tala Nagari Industrial Area, Aligarh(UP)-202001



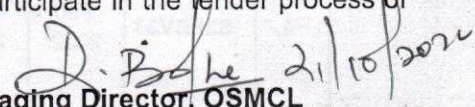
In view of the above Ms. SWAROOP PHARMACEUTICALS PVT. LTD., was issued with Show Cause Notice (SCN) vide this office letter No. 6597, Dt. 13/09/2022 seeking explanation within seven (07) days of receipt of the letter as to why it shall not be de-recognised/ debarred for the item I.V. Compound Sodium Lactate (Ringers Lactate) RL as per PO Clause No. 5(h) (ii) read with Bid Condition No. 6.38.1 (ii) of Bid reference No. OSMCL/2021-22/DRUGS-DHS-GEN-GR-I/01.

In response to the SCN, the supplier vides his letter dtd. 17/09/2022 has replied that,

- They have supplied I.V. Compound Sodium Lactate (Ringers Lactate) RL to OSMCL, which were accepted and distributed by OSMCL after sending their samples to NABL accredited laboratories and find them as of 'Standard Quality' as per prescribed specification vide test report received from NABL accredited laboratories.
- In reply to show cause notice received from Drug Inspector for the NSQ reports we have notified out intimation to under section 25 (3) of Drugs and Cosmetics Act adducting evidence in controversion of the government analysis report and requested to send the sample to Director Central Drug Laboratory, Kolkata for fresh test and analysis, copies of the letter to Drugs Inspector are enclosed as Annexure.
- As per condition of the tender Ref. No. OSMCL/2021-22/DRUGS-DHS-GEN-GR-I/01. It is stated in clause 6.29 quality testing sub clause 6.29.10 that "After being released for public distribution, if any statutory sample of OSMCL supply drug is drawn by Drugs Control Department of the state on suo-motto basis or on complaint or drawn by officers of CDSCO and if it is declared as Not of Standard Quality (NSQ), the report is conclusive till it is challenged by supplier/ company. If it is challenged, then the report of Director, CDL, Kolkata shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of debarring of product or company".
- According to the condition mentioned mentioned in para 04 the NSQ reports received from Government Analyst are not conclusive evidence since these have been challenged under the provisions of the Drugs and Cosmetic Act. These cannot be considered till the sample have not been tested by Director, Central Laboratory, Kolkata.
- In view of above context and basing on the final conclusive report from Central Drug Laboratory, Kolkata (the appellate laboratory) the reply of the alleged firm in response to SCN issued is not sustainable in the eye of law, therefore liable to be rejected.

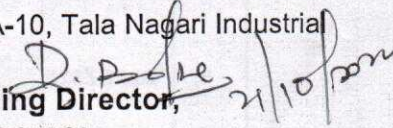
That as per PO Clause No. 5(h) (ii) read with Clause No. 6.38.1(ii) of Bid Reference No. OSMCL/2021-22/DRUGS-DHS-GEN-GR-I/01, **Ms. SWAROOP PHARMACEUTICALS PVT. LTD.**, A-10, Tala Nagari Industrial Area, Aligarh(UP)- 202001 is hereby, de-recognised/debarred for the item I.V. Compound Sodium Lactate (Ringers Lactate) RL for a period of three (03) successive years from the date of issue of this order.

The Performance Security/ Bank Guarantee / EMD amount submitted by the firm for the said item is hereby, forfeited & the firm shall not be allowed to participate in the tender process of Odisha State Medical Corporation Ltd. for the said item.


Managing Director, OSMCL

Memo No. 8080 /Dt. 21.10.2022

Copy forwarded to Ms. SWAROOP PHARMACEUTICALS PVT. LTD., A-10, Tala Nagari Industrial Area, Aligarh(UP)- 202001 for information.


Managing Director,
OSMCL

Memo No. 8081 /Dt. 21.10.2022

Copy submitted to the Principal Secretary to Govt., H & FW Dept. Odisha, for favour of kind information.

D. Bhe 21/10/2022
Managing Director,
OSMCL

Memo No. 8082 /Dt. 21.10.2022

Copy forwarded to DHS/DMET, Odisha for information and necessary action.

D. Bhe 21/10/2022
Managing Director,
OSMCL

Memo No. 8083 /Dt. 21.10.2022

Copy forwarded to the Commissioner-cum-Secretary to Govt., H & FW Dept. Odisha, for favour of kind information.

D. Bhe 21/10/2022
Managing Director,
OSMCL

Memo No. 8084 /Dt. 21.10.2022

Copy forwarded to the GM – Operation (D & S) / GM (F & A), OSMC for information and necessary action.

D. Bhe 21/10/2022
Managing Director,
OSMCL

Memo No. 8085 /Dt. 21.10.2022

Copy forwarded to IT Cell, OSMC for information and necessary action.

D. Bhe 21/10/2022
Managing Director,
OSMCL