



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

(Assuring Quality, Saving lives)

OSMCL-QA-MISC-0047-2022 Letter No. 8699/OSMCL/QA/I-011/2022 Date. 11-11-2022

ORDER

Ms. IVES DRUGS INDIA PVT. LTD, Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-452001 (Madhya Pradesh) was placed with orders to supply **I.V. Compound Sodium Lactate IP (Ringer's Lactate) RL 500ml** vide **Purchase Order No. CR23242** Dtd. 28.05.2021, CR24070 Dtd. 15.09.2021 and CR24693 Dtd. 22.11.2021. The firm has supplied the drug in number of batches, out of which four (04) number of batches have been declared as **"Not of Standard Quality (NSQ)"** by the **Govt. Analyst CDL, Kolkata**, which have been communicated to the supplier with enclosed copies of test reports vide this office letter no. 1307 Dtd. 04/03/2022, 6733 Dtd. 15/09/2022, 6245 Dtd. 30/08/2022 and 7060 Dtd. 27/09/2022 under intimation to the The Controller Food and Drug Administration, Idgah Hill, Bhopal, Madhya Pradesh-462001. The details of batches of the subject drug and the reason for declaring the said batches as **"NSQ"** are mentioned below;

Sl. No.	Item Name	Batch No.	Mfg. Dt.	Exp. Dt.	Ref. PO. No. & Date	Status	Reason for declaring NSQ	Mfd. By
1.	D29003- I.V. Compound Sodium Lactate (Ringer's Lactate) RL	107008	Jul-2021	Jun-2023	CR23242 Dt.28.05.2021	NSQ	The subject batch does not conform to I.P. with respect to the test for "Sterility" vide test report no. 17-2/2021-SS/OR-12/2177.	Ms. Ives Drugs India Pvt. Ltd. Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1
2.	D29003- I.V. Compound Sodium Lactate (Ringer's Lactate) RL	110070	Oct-2021	Sep-2023	CR24070 Dt.15.09.2021	NSQ	The subject batch does not conform to I.P. with respect to the test for "Bacterial Endotoxins" and "Sterility" vide test report no. 17-2/2022-SS/OR-05/516.	Ms. Ives Drugs India Pvt. Ltd. Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1
3.	D29003- I.V. Compound Sodium Lactate (Ringer's Lactate) RL	112036	Dec-2021	Nov-2023	CR24693 Dt.22.11.2021	NSQ	The subject batch does not conform to I.P. with respect to the test for "Sterility" vide test report no. 17-2/2022-SS/OR-14/1301.	Ms. Ives Drugs India Pvt. Ltd. Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1
4.	D29003- I.V. Compound Sodium Lactate (Ringer's Lactate) RL	112038	Dec-2021	Nov-2023	CR24693 Dt.22.11.2021	NSQ	The subject batch does not conform to I.P. with respect to the test for "Bacterial Endotoxins" and "Sterility", vide test report no. 17-2/2022-SS/OR-24/1582.	Ms. Ives Drugs India Pvt. Ltd. Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1

In view of the above **Ms. IVES DRUGS INDIA PVT. LTD** was issued with Show Cause Notice (SCN) vide this office letter No.8076, Dt. 21/10/2022 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 IP (Ringer's Lactate) RL 500ml** 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 reply, the supplier has denied the test reports of the Govt. Analyst, CDL, Kolkata and challenged the same for repeat testing.



However, OSMCL has received a Blacklisting Order No.8433 Dtd.21.10.2022 from Madhya Pradesh Public Health Service Corporation Ltd.(MPPHSCL), Bhopal for the supply of said item name-**I.V. Compound Sodium Lactate IP (Ringer's Lactate) RL 500ml** and the alleged firm has been blacklisted for the period of three (03) years from the date of issue of the order.

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 is not acceptable and therefore liable to be rejected.

Hence, as per terms and conditions of PO Clause No. 5(h) (ii) read with Bid Clause No. 6.38.1(ii) of Bid Reference No. OSMCL/2021-22/DRUGS-DHS-GEN-GR-I/01, **Ms. IVES DRUGS INDIA PVT. LTD**, Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1 is hereby, de-recognised /debarred for the item **I.V. Compound Sodium Lactate IP (Ringer's Lactate) RL 500ml** 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. (OSMCL) for the above said item.


Dr. Poma Tudu, I.A.S
Managing Director, OSMCL

Memo No. 8700 /Dt. 11-11-2022

Copy forwarded to M/s. IVES DRUGS INDIA PVT. LTD, Works, Ghatabillod, Dist. Dhar, H.O. 504, Chetak Center, R.N.T, Marg, Indore-1 for information.


Managing Director, OSMCL

Memo No. 8701 /Dt. 11-11-2022

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


Managing Director, OSMCL

Memo No. 8702 /Dt. 11-11-2022

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


Managing Director, OSMCL

Memo No. 8703 /Dt. 11-11-2022

Copy forwarded to the Drugs Controller, Odisha for information and necessary action.


Managing Director, OSMCL

Memo No. 8704 /Dt. 11-11-2022

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

Managing Director, OSMCL

Handwritten signature and date: 11/11/22

Memo No. 8705 /Dt. 11-11-2022

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

Managing Director, OSMCL

Handwritten signature and date: 11/11/22