



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking & ISO 9001:2015 Certified)

(Assuring Quality, Saving lives)

File No. OSMCL-QA-MISC-0030-2024 Letter No. 1397 OSMCL/QA/VI-019-2024 Date. 17-02-2025

ORDER

M/s ALLIAANCE BIOTECH, SCO-84, Sec-5, Mansa Devi Complex, Panchkula (HR)-134114, was placed with order to supply of item- D21025-Inj. Rabeprazole (I.V) (with diluents in plastic container), 20mg/vial, vide Purchase Order No. CR29119 Dt.03.04.2023. The firm have supplied the drug in number of batches, out of which, from two (02) batches, one batch (B.No.AGI-23216) has been declared as "Not of Standard Quality (NSQ)" and deemed to be "SPURIOUS" and another batch (B.No.-AGI-23217) has been declared as "Not of Standard Quality (NSQ)" by Govt. Analyst, CDL, Kolkata, which have been communicated to the supplier with enclosed copies of test reports vide this office letter no. 193 Dtd.08.01.2025 under intimation to the State Drugs Controller, Controlling-cum-Licensing Authority, Baddi, Dist.-Solan, Himachal Pradesh-173205. The details of the batches of the subject drug and the reason for declaring the said batches as "NSQ" and "SPURIOUS" are mentioned below;

Sl. No.	Item Name	Batch No.	Mfg. Dt.	Exp. Dt.	Status	Mfg. By	CDL, Kolkata report No.	Reason for NSQ
01.	D21025-Inj. Rabeprazole (I.V)(with diluents in plastic container),20mg/vial	AGI-23216	Jun-2023	May-2025	NSQ	Ms. Alliaance Biotech, 440/3,Vill-Katha,Baddi, Solan(H.P.)-173205	KOL/LS/2024-25/1365	The sample does not conforms to IP with respect to test for "Sterility", "Clarity of Solution", "Particulate matter", "Identification" and "Assay of Rabeprazole Sodium" and is also not of standard quality for the reason stated under "Description". The sample is deemed to be "SPURIOUS" as per the section 17B of Drugs and Cosmetics Act.
02.	D21025-Inj. Rabeprazole (I.V)(with diluents in plastic container)20mg/vial	AGI-23217	Jun-2023	May-2025	NSQ	Ms. Alliaance Biotech, 440/3,Vill-Katha,Baddi, Solan(H.P.)-173205	KOL/LS/2024-25/1366	The sample does not conforms to IP with respect to test "pH", "Clarity of Solution", "Particulate matter", "Assay of Rabeprazole Sodium" and is also not of standard quality for the reason stated under "Description".

In view of the above M/s ALLIAANCE BIOTECH, SCO-84, Sec-5, Mansa Devi Complex, Panchkula (HR)-134114, was issued with Show Cause Notice (SCN) vide this office letter No.338, Dt.15.01.2025 seeking explanation within seven (07) days of receipt of the letter as to why the item- D21025-Inj. Rabeprazole (I.V) (with diluents in plastic container) 20mg/vial, supplied by the firm M/s ALLIAANCE BIOTECH, SCO-84, Sec-5, Mansa Devi Complex, Panchkula (HR)-134114, having manufacturing unit at Katha, Baddi, Solan (H.P.)- 173205, shall not be De-recognised / Debarred in accordance with 34th Board meeting Agenda No.9 (B) (a);

In response to the SCN, the supplier has replied vide his Ref. File No.-AB/QA/01-25/09 Dtd.16.01.2025, that,

- The said Drugs were manufactured and supplied after proper testing and was found to be Standard quality.
- The firm do not agree with the test report of Central Drugs Laboratory, Kolkata.
- The firm intimated to Odisha State Medical Corporation Ltd. for recall back the above supplied drugs.

In pursuant to the section 25(4) of the Drugs Act 1940, the test report of Govt Analyst, Central Drug Laboratory (CDL), Kolkata is final and conclusive. Hence the explanations of the Supplier to the Show cause Notice served vide this office letter No-338, Dt-15/1/25 is not acceptable.

Therefore, as per the 34th Board meeting Agenda No.9 (B) (a), M/s ALLIAANCE BIOTECH, SCO-84, Sec-5, Mansa Devi Complex, Panchkula (HR)-134114 having manufacturing unit at Katha, Baddi, Solan (H.P.)- 173205, is hereby De-recognised / Debarred, for the item- D21025-. Rabeprazole Injection IP(with diluents in plastic container), 20mg/vial, for a period of 7 years with immediate effect.

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.

Poma Tudu

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

Memo No. 1398 /Dt. 17-02-2025

Copy forwarded to M/s ALLIAANCE BIOTECH, SCO-84, Sec-5, Mansa Devi Complex, Panchkula (HR)-134114 for information.

Poma Tudu

Managing Director, OSMCL

Memo No. 1399 /Dt. 17-02-2025

Copy forwarded to the State Drugs Controller, Controlling-cum-Licensing Authority H.B. Baddi, Dist.Solan-173205 for information and necessary action.

Poma Tudu

Managing Director, OSMCL

Memo No. 1400 /Dt. 17-02-2025

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

Poma Tudu

Managing Director, OSMCL

Memo No. 1401 /Dt. 17-02-2025

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

Poma Tudu

Managing Director, OSMCL

Memo No. 1402 /Dt. 17-02-2025

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

Pamuly

Managing Director, OSMCL

Memo No. 1403 /Dt. 17-02-2025

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

Pamuly

Managing Director, OSMCL

Memo No. 1404 /Dt. 17-02-2025

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

Pamuly

Managing Director, OSMCL

