



ODISHA STATE MEDICAL CORPORATION LTD.

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

(Assuring Quality, Saving lives)

File No. OSMCL-QA-MISC-0043-2024 Letter No. 2146/ OSMCL/QA/I-012/2024

Date. 05-03-2025

ORDER

Ms. Gnosis Pharmaceuticals Pvt. Ltd., B-102, 1st Floor, Pushpanjali Enclave, Outer Ring Road, Opposite Pillar No.39, Pitampura, New Delhi-110034, was placed with order to supply Lotion Permethrin 5% w/v, 60ml, vide **Purchase Order No. CR31545** Dtd.13.06.2024. 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 majority of empanelled laboratories, which have been communicated to the supplier with enclosed copies of test reports vide this office letter no. 9260 Dtd. 23.12.2024 under intimation to The Assistant Drugs Controller-cum-Licensing Authority, HQ-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**" are mentioned below;

Sl. No.	Item Name	Batch No.	Mfg. Dt.	Exp. Dt.	PO. No. with date	Status	Reason for declaring NSQ	Mfd. By
1.	D18011- Lotion Permethrin 5% w/v, 60ml	GO400089	Jun-2024	May-2026	CR31545 Dtd.13.06.2024	NSQ	The sample does not comply w.r.t "Microbial Contamination test".	Ms. Gnosis Pharmaceuticals Pvt Ltd., Nahan Road, Village-Moginand, Kala Amb, Dist.Sirmour (HP)-173030
2.		GO400091	Jun-2024	May-2026				
3.		GO400098	Jun-2024	May-2026				
4.		GO400103	Jul-2024	Jun-2026				

In view of the above **Ms. Gnosis Pharmaceuticals Pvt. Ltd.** was issued with Show Cause Notice (SCN) vide this office letter No.191, Dt.08.01.2025 seeking explanation within seven (07) days of receipt of the letter as to why the item- D18011- Lotion Permethrin 5% w/v, 60ml, supplied by the firm **Ms. Gnosis Pharmaceuticals Pvt. Ltd.** having manufacturing unit at Nahan Road, Village-Moginand, Kala Amb, Dist. Sirmour (HP)-173030, shall not be De-recognised /Debarred in accordance with PO Clause No. 5(h) (ii) read with Bid Condition No. 6.38.1 (ii) of Bid reference No. OSMCL /2023-24/DRUGS-DHS-GEN-GR-I/02.

In response to the SCN, the supplier vide his letter Ref.No. GNOS/OSMCL/C-1 Dtd.10.01.2025 has replied that,

- The firm has submitted that their quality control department has examined the samples of the product Lotion Permethrin 5%w/v,60ml bearing batch No.G0400089, G0400091, G0400098 and G0400103 from its controlled sample and found that it complies with all quality Standards.
- It is further submitted that the exposure to heat and moisture has detrimental effect on the stability of pharmaceutical products and its storage conditions and handling play an important role in its stability and may further cause microbial contamination.

- As per the standard Storage conditions, mentioned on the carton, the subject medicine was to be stored in a cool place as prescribed in Schedule P of the Drugs and Cosmetics Rules, 1945 (the Rules, for short), Permethrin lotion should be stored at room temperature, between 20° C to 25° C. Store in a cool, dry place.
- It is further added that exposure of medicine to heat/moisture has a detrimental effect on the stability of pharmaceutical products and medicine. There are all possibility that the said defects arising out of variations from the prescribed standards due to improper storage may during transport or at distribution level.
- However, without going in the intricacies of subject matter, we wish to replace all the 4 batches mentioned above with fresh new batches.

In view of above context and basing on the final conclusive report from majority of empanelled laboratories, the reply of the alleged firm in response to SCN issued is not acceptable. Since, if storage condition of a drug is not mentioned in Schedule-P, the same has to be stored under normal room temperature as per Schedule-P. So Lotion Permethrin to be stored at normal room temperature as per Schedule-P read with Rule-96 of Drugs Rule 1945.

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/2023-24/DRUGS-DHS-GEN-GR-I/02, the firm **M/s Gnosis Pharmaceuticals Pvt. Ltd.**, B-102, 1st Floor, Pushpanjali Enclave, Outer Ring Road, Opposite Pillar No.39, Pitampura, New Delhi-110034 having manufacturing unit at Nahan Road, Village - Moginand, Kala Amb, Dist. Sirmour (HP)-173030, is hereby De-recognised /Debarred, for the item-D18011-Lotion Permethrin 5% w/v, 60ml, for a period of three (3) 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.

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

Memo No. 2147 /Dt. 05-03-2025

Copy forwarded to M/s. Gnosis Pharmaceuticals Pvt. Ltd. India Pvt. Ltd, B-102, 1st Floor, Pushpanjali Enclave, Outer Ring Road, Opposite Pillar No.39, Pitampura, New Delhi-110034 for information

Panna Tudu
Managing Director, OSMCL

Memo No. 2148 /Dt. 05-03-2025

Copy forwarded to the Assistant Drugs Controller -cum-Licensing Authority, HQ-Baddi, Dist.-Solan, Himachal Pradesh-173205 for information and necessary action.

Panna Tudu
Managing Director, OSMCL

Memo No. 2149 /Dt. 05-03-2025

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

Panna Tudu
Managing Director, OSMCL

Memo No. 2150 /Dt. 05-03-2025

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

Panna Tudu
Managing Director, OSMCL

Memo No. 2151 /Dt. 05-03-2025

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

Pamunty

Managing Director, OSMCL

Memo No. 2152 /Dt. 05-03-2025

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

Pamunty

Managing Director, OSMCL

Memo No. 2153 /Dt. 05-03-2025

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

Pamunty

Managing Director, OSMCL

