C

Sample Name LORAZEPAM INJECTION-IP.

Submitted By Quality Control Advisor. (MMDSL) Shillong. Report No

DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. Receipt Date 19-Sep-24 Address

Mfg By N.S.

Supplied By N.S.

Mfg. Date Batch No 07/2024 MMDSL/QC-0495

Exp Date 06/2026

Batch Size N.S.

Mfg Lic No

Ref No

- N.S. Sample Qty 30 AMPOULES

Report Date 07-Oct-24

TEST RESULTS

Date / Period of Performance of test 19/09/2024 to 07/10/2024.

Reference to protocol :- I.P-2022.

Description

:- Clear colourless solution filled in amber colour

glass ampoules.

Identification(by HPLC) :- Complies.

Lorazepam related compound B:- Not detected ·

Limit:NMT 0.1%

(by HPLC)

Related Substances (by HPLC) :- Complies.

Extractable volume :- 2.04ml.

Particulate matter

:- Complies.

Sterility

:- Complies with the test for sterility.

Bacterial endotoxins :- Less than 100.0EU/mg of Lorazepam

Limit NMT 100.0EU/mg of Lorazepam.

Assay (by HPLC)

:- Each ml. contains:-

Obtained Claim Lower

Method Upper

Lorazepam

Contents of

:- 1.98mg 2.0mg. 1.8mg.

2.2mg.

LIMIT

IP.

NOTE: - SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample refer as defined in the Act and the rules made there under per IP.