

Sample Name MIDAZOLAM INJECTION-IP.1.0mg/ml. **Mfg Lic No** [REDACTED]
Submitted By Quality Control Advisor. (MMDSL) Shillong. **Report No** [REDACTED]
Address DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. **Receipt Date** 19-Sep-24
Mfg By N.S. **Report Date** 05-Oct-24
Supplied By N.S. **Ref No** N.S.
Batch No MMDSL/QC-0496 **Mfg. Date** 07/2024 **Exp Date** 06/2026 **Batch Size** N.S. **Sample Qty** 30 VIALS

TEST RESULTS

Date / Period of Performance of test 19/09/2024 to 05/10/2024.

Reference to protocol :- I.P-2022.

Description :- Clear colourless solution filled in transparent glass vials.

Identification (by I.R) :- Complies.

| | | LIMIT | |
|----|---------|-------|-------|
| | | Lower | Upper |
| pH | :- 3.19 | 2.9 | 3.7 |

Related substances (by HPLC):- Complies.

Extractable volume :- 5.06

Sterility :- Complies with the test for sterility.

Bacterial endotoxins :- Less than 8.33EU/mg of midazolam Limit:-NMT 8.33EU/mg of midazolam

Particulate matter :- Complies.

Assay (by HPLC) :- Each ml. contains:-

| Contents of | Obtained | Claim | LIMIT | | Method |
|-------------|------------|--------|---------|---------|--------|
| | | | Lower | Upper | |
| Midazolam | :- 0.995mg | 1.0mg. | 0.95mg. | 1.05mg. | IP. |

NOTE:- SAMPLE CONSUMED IN TESTING.

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

