Sample Name PANTOPRAZOLE FOR INJECTION-IP. 40mg. Mfg Lic No Submitted By Quality Control Advisor. (MMDSL) Shillong. Report No

Address DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya.

Mfg By N.S.

Supplied By N.S.

Batch No Mfg. Date MMDSL/QC-0507 08/2024

nkhrahNHM,EastKhasi Hills Meghalay

**Exp Date** 07/2027

Batch Size N.S.

Ref No

LIMIT

N.S.
Sample Qty
30 VIALS.

Receipt Date 09-Oct-24

Report Date 28-Oct-24

## **TEST RESULTS**

Date / Period of Performance of test 09/10/2024 to 28/10/2024.

Reference to protocol :- IP-2022. Addendum 2024

Description :- White powder filled in amber colour glass vials.

Identification A (by IR) :- Complies.

B (by HPLC) :- Complies.
C :- Complies.

Average fill weight :- 127.0mg.
Uniformity of fill weight :- Within limit.

Limit

Dower Upper pH(of 0.4% soln.) :- 9.78 9.0 11.5

Particulate matter :- Complies.

(after reconstitution)

Appearance of solution :- Complies.
Clarity of solution :- Complies.

(after reconstitution)

Related substances (by HPLC) :- Complies.

Sterility :- Complies with the test for sterility.

Assay (by HPLC) :- Each vial contains:-

Content of Obtained Claim Lower Upper Method

Sterile Pantoprazole Sodium

eqv. to anhydrous

Pantoprazole :- 39.86mg 40.0mg 37.20mg 42.00mg IP.

NOTE: - SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.