

Sample Name	PANTOPRAZOLE FOR INJECTION-IP. 40mg.	Mfg Lic No	[REDACTED]
Submitted By	Quality Control Advisor. (MMDSL) Shillong.	Report No	[REDACTED]
Address	DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya.	Receipt Date	09-Oct-24
Mfg By	N.S.	Report Date	28-Oct-24
Supplied By	N.S.	Ref No	N.S.
Batch No	Mfg. Date	Exp Date	Batch Size
MMDSL/QC-0506	08/2024	07/2027	N.S.
			Sample Qty
			30 VIALS.

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 :- 124.8mg.
 Uniformity of fill weight :- Within limit.

		Limit	
		Lower	Upper
pH(of 0.4% soln.)	:- 9.87	9.0	11.5
Particulate matter (after reconstitution)	:- Complies.		
Appearance of solution	:- Complies.		
Clarity of solution (after reconstitution)	:- Complies.		
Related substances(by HPLC)	:- Complies.		

Sterility :- Complies with the test for sterility.

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

	Obtained	Claim	Lower	Upper	Method
Content of Sterile Pantoprazole Sodium eqv. to anhydrous Pantoprazole	:- 39.98mg	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.