



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : Pantaburg-I.V. 40 mg Pantoprazole for injection 40 mg	
Batch No. : GD25D-02D	Mfg. Date : 04/2025
Batch Size : 20881 Vials	Exp. Date : 03/2027
Sample Qty. : 50 Vials	Analytical Report No : GFP20250127
Date of Receiving : 20/04/2025	Date of Completion : 29/04/2025
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations	
1.	Description	A white or almost white hygroscopic powder filled in 10 ml amber color glass vial.	Almost white hygroscopic powder filled in 10 ml amber color glass vial.	
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution should be correspond to the peak in the chromatogram obtained with the reference solution.	Complies	
3.	Uniformity of weight	± 10.0 % of the average fill weight	Complies	
4.	Average fill Weight	122.26 mg ± 2%	121.77 mg	
5.	pH (10% w/v solution)	Between (9.0 to 12.0)	10.10	
6.	Water	NMT 3.0 %w/w	2.05 %	
7.	Clarity of solution	A. The solid dissolves completely leaving no visible residue as undissolved matter.	Complies	
		B. The constituted solution shall not be significantly less clear than an equal volume of the diluents or water for injection contained in a similar vessel and examined similarly.	Complies	
8.	Particulate Matter			
	A. BY Visual inspection	(I)	Solution should be clear	Complies
		(II)	Constitute the injection as directed on the label: the solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies
	B. By LPC	≥ 10µm	NMT 6000 particles/ container	Less than 6000 particles / container
≥ 25µm		NMT 600 particles/ container	Less than 600 particles / container	
9.	Sterility	Should be Sterile	Under analysis	
10.	Bacterial Endotoxins	NMT 1.25 EU/mg of Pantoprazole	Less than 1.25 EU/mg Pantoprazole.	
11.	Assay : Each glass vial contains:-			

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Pantoprazole Sodium (Sterile-Lyophilized) Eq. to Pantoprazole.	40 mg	39.2164 mg	98.04 %	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample submitted ~~complies/does not comply~~ with the prescribed standard/~~not standard~~ of quality, as according to IHS with respect to the above test only.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	
Designation	Executive	Sr. Executive	
Sign/ Date	<i>[Signature]</i> 29/04/2025	<i>[Signature]</i> 29/04/2025	

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