



CAPTAB BIOTEC UNIT II

PLOT No. 125, EPIP ROAD, MAUJA JHARMAJRI, BADDI, DISTT. - SOLAN (H.P)

PROVISIONAL CERTIFICATE OF ANALYSIS-FINISHED PRODUCTS

Product Name	PANTABURG-I.V (Pantoprazole for Injection)		
B. No.	DI19G0233	A. R. No.:	CTBFPDIGL0519057
Mfg. date:	05/2019	Date of received:	25/05/2019
Exp. date:	10/2020	Date of Analysis:	25/05/2019
Batch Size:	25,000 Vials	Date of completion:	25/05/2019
Sample quantity:	42 Vials	Release date	25/05/2019

S. No.	TESTS	SPECIFICATION	RESULT
01.	Description	A white or almost white powder filled in amber glass vial closed with rubber plug and sealed with flip-off aluminium cap.	A white powder filled in amber glass vial closed with rubber plug and sealed with flip-off aluminium cap.
02.	Identification	To be positive for Pantoprazole Sodium	Complies
03.	Appearance of solution	The Solution should be clear having no visible residue as undissolved matter.	Complies.
04.	Particulate matter	The reconstituted solution should be free from foreign particles on visual inspection.	Complies
05.	pH	Between 9.0 to 12.0	9.88
06.	Average filled weight	160 mg; \pm 5%	159.6 mg
07.	Uniformity of weight	Not more than two of the individual weights deviate from the average weight by more than 10% and none deviates by more than twice that percentage.	Complies
08.	Sterility	Should be comply the test for sterility.	Under Test
09.	Bacterial Endotoxin Test	Not more than 1.25 Endotoxin unit/mg	Complies
10.	Assay: Each vial contains:- Sterile Pantoprazole Sodium I.P eq. to Pantoprazole 40 mg	36.00 mg to 44.00 mg (90.00 % to 110.00 %)	40.51 mg (101.28%)

Remark: The Sample complies/does not comply with I.H / I.P Specifications with respect to above test & Sterility is under test.

Analysed By Sign/Date 25/05/2019	Checked By Sign/Date 25/05/2019	Approved By Sign/Date 25/05/2019
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