



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Rabezcan 20	A.R. No.	FG/G/24A0134
Generic Name	Rabeprazole Injection IP 20 mg	Sample Quantity	65 Vials
Batch No.:	AGD41010	Sample Received on	26/10/2024
Batch Size:	0.50 Lac	Analysis Date	26/10/2024
Mfg. Date.	10/2024	Release Date	09/11/2024
Exp. Date	09/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White or off white lyophilized powder, hygroscopic, filled in 10 ml amber colour molded glass vial plugged with rubber stopper and sealed with green coloured flip off having aluminium seal.	White lyophilized powder, hygroscopic, filled in 10 ml amber colour molded glass vial plugged with rubber stopper and sealed with green coloured flip off having aluminium seal.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight.	83.24 mg		
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 81.21 mg ; Max: 86.04 mg -2.44% ; + 3.36%		
5.	Reconstitution Solution	When reconstitution with the sterile water for injection the sample solution should be clear and free from suspended matters.	Clear Solution.		
6.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.		
7.	pH	Between 10.8 to 12.5	11.08		
8.	Water	NMT 7.0%w/w	1.74%w/w		
9.	Particulate matter	The Sample Solution should be clear and free from any visible particles.	The Sample Solution is clear and free from any visible particles.		
10.	Bacterial Endotoxins	Not more than 5.0 EU/mg	Less than 5.0 EU/mg		
11.	Sterility	Should be sterile	Sterile		
12.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Rabeprazole sodium IP Eq. to Rabeprazole (As Lyophilized powder)	20 mg	Between 90.0 % to 110.0 % of labeled amount of Rabeprazole. (Between 18.0 mg to 22.0 mg)	19.63 mg	98.15%

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In- House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Ram Awadh Yadav
Designation	Executive	Head QC	Head QA
Signature			
Date	09/11/2024	09/11/2024	11/11/2024