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/24A0116
Generic Name	Rabeprazole Injection IP 20 mg	**Sample Quantity**	65 Vials
Batch No.:	AGD41002	**Sample Received on**	05/10/2024
Batch Size:	0.50 Lac	**Analysis Date**	05/10/2024
Mfg. Date.	10/2024	**Release Date**	19/10/2024
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**	± 7.5% of Target filled weight.	83.24 mg
4.	**Uniformity of filled weight**	± 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	11.46
8.	**Water**	NMT 7.0%w/w	2.88%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)	19.61 mg	98.05%

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	Ankit Kumar Rai	Bakhshish Singh
Designation	Executive	Executive	Plant Head
Signature			
Date	19/10/2024	19/10/2024	19/10/2024