



ORISON PHARMA INTERNATIONAL,
Vill, Khari, kala Amb (H.P)

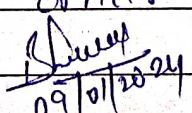
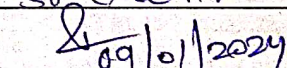
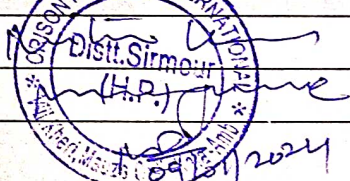
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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	RABEZCAN – 20	A.R. No.	OPI-FGT5116/23
Generic Name	Rabeprazole Sodium Tablets IP	Received date	08/01/2024
Batch No.	23I – T2038K	Analysis Completion /Release Date	09/01/2024
Mfg. Date	12/2023	Batch Size	1.50 Lac Tablets
Best Before /Expiry	11/2025	Mfg. Lic. No.	MNB/07/644 & MB/07/645

Sr. No.	Test	Specifications	Results
1.	Description	Brick red colour, round shape, biconvex both side plain enteric coated tablet.	Brick red colour, round shape, biconvex both side plain enteric coated tablet.
2.	Identification		
2.1	By HPLC	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 (a).	Complies
3.	Average wt. of tablet	200.0 mg \pm 7.5% (185.0 mg to 215.0 mg)	194.8 mg
4.	Uniformity of wt	Average weight. \pm 7.5%	Max +4.72% Min -1.43%
5.	Dissolution Test		
5.1	In Acid Medium	NMT 10% of the stated amount	Min – 3.27% & Max +4.79%
5.2	In buffer Medium	NLT 75% of the stated amount	Min – 88.22% & Max +92.09%
6.	Disintegration Time	2 hour in 0.1 M HCL 1 Hour in phosphate buffer pH 6.8	2 hour 0.1 m HCL & 16 minutes (mixed phosphate buffer)
7.	Related Substance	Should be comply as per IP	Complies
8.	Uniformity of content	85% to 115%	Complies
9.	ASSAY :- (Each enteric coated tablet contains)		
9.1	Rabeprazole Sodium IP 20 mg	18.0 mg to 22.0 mg & 90% to 110%	19.67 mg & 98.35%

Remark:- In the opinion of the undersigned the sample referred to above is standard quality as complies as per IP/BP/USP/HH Specification.

Signatories	Prepared By (QC)	Checked By (QC)	Approved By (QC)
Name	Khansu	Rizwan	Distt. Sirmour (H.P.)
Designation	Officer	Sr. Executive	
Signature & Date:	 09/01/2024	 09/01/2024	 09/01/2024

OPI/QC/057/F05-00