



Nixi Laboratories Pvt. Ltd.
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	RABEZCAN 20	AR. No.	NL/DI/FG/26/584
Generic Name	Rabeprazole Sodium Injection IP		
Mother Batch No.	D26AB006	Reference	IP
Child Batch No.	D26AB006D	Batch Size	50200 Vials
Mfg. Date	06/2026	Exp. Date	05/2028
Specification No. (STS No.)	QC/DPI/FG/STS/020	Standard Test Procedure No.	QC/DPI/FG/STP/020
Sampled Quantity	70 Vials	Sampling Date	17/06/2026
Release Date	02/07/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	White to off white powder filled in 10 ml amber / clear colour glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.	White powder filled in 10ml Amber colour glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.
2.	Identification: 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.	Complies
3.	Clarity of solution	a) The solid dissolves completely, leaving no visible residue as undissolved matter. b) The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner. The reconstitutes time is 180 seconds maximum	Complies
4.	Average filled weight	Filled Weight $\pm$ 5%	74.17 mg
5.	Uniformity of content	Average Filled Weight $\pm$ 5%	-2.39% to +2.33%
6.	pH (0.8% w/v of solution)	10.80 to 12.50	11.55

7.	Particulate matter		
	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr.Executive QC	Assistant Manager QC
Signature			
Date	02/07/26	02/07/26	02/07/26



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Sr.No.	TEST	SPECIFICATION	OBSERVATION
	For Visible Particles	Should be free from visible particles	Complies
	For sub visible particles: (i) Equal to or greater than 10µm (ii) Equal to or greater than 25µm	NMT 6000 particle/container NMT600 particle/container	97.0 particle/container 1.0 particle/container
8.	Sterility	Should comply the test of sterility	Complies
9.	Bacterial Endotoxins	NMT- 5 EU/mg of Rabeprazole Sodium	Complies
10.	Water Content	Not more than 6.0%	0.98%
11.	Related Substances		
	(i) Rabeprazole sulphide	Not More Than 1.0%	0.22%
	(ii) Rabeprazole sulphone	Not More Than 1.0%	0.064%
	(iii) Any secondary impurity	Not More Than 0.5%	0.041%
	(iv) Sum of all other impurity	Not More Than 2.5%	0.483%
12.	Assay		
	Each vial contains: Rabeprazole Sodium IP 20 mg (As Lyophilized Powder).	18.00 mg to 22.00 mg (90.00 % To 110.00 %)	20.66 mg (103.30 %)

Result: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No- QC/DPI/FG/STS/020.

Conclusion : In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr.Executive QC	Asst. Manager QC
Signature			
Date	02/07/26	02/07/26	02/07/26