

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	CLARICAN 500MG Injection	A.R. No.	NB/FP/24/406
Generic Name	Clarithromycin for Infusion BP 500mg	Sampled qty.	45 vials
Batch No.	N24382E	Sampled by	Rakesh
Batch Size	1000 Vials	Sampled on	27/03/2025
Mfg. Date	03/2025	Date of Testing	27/03/2025
Exp. Date	02/2027	Date of Release	11/04/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Clarithromycin working standard.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-5.04% & +5.25%
4.	Average weight	Informative.	840.6 mg
5.	Clarity & Colour of solution	A solution is not more opalescent than reference suspension II, And not more intensely coloured than reference solution Y ₇ .	Complies
6.	Related Substance		
	Area of any secondary peaks	NMT- 1.0%	Not detected
	Not more than four such peaks	NMT- 0.4%	Not detected
	Sum of areas of all secondary peaks	NMT- 3.5%	Not detected
7.	pH	4.0 to 6.0	5.59
8.	Water	NMT-3.0% w/w	2.18% w/w
9.	Particulate matter		
	a.) Visible particulate matter	Should Free from any type of visual particles	Complies
	(b.) Sub-Visible particle count		
	(i.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	1804/vial
(ii.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	19/vial	
10.	Sterility	No microbial growth should be observed.	Complies

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: SWATI DHAWAN



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11.	Bacterial Endotoxins	NMT 0.20 EU/mg of Clarithromycin.	of	Less than 0.20 EU/mg of Clarithromycin.
12.	Assay: Each glass vial Contains :			
Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Clarithromycin (Sterile) Lyophilized	IP 500 mg	517.49 mg	103.50%	95.0% to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/BP/USP/IHS.

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