

**AMERICAN REMEDIES HEALTHCARE PVT.LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

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Certificate of Analysis Finished Product

Product Name	CLARICAN Injection	A.R. No.	ARN/FP/25/092
Generic Name	Clarithromycin for Infusion BP 500mg	Sampled qty.	45 vials
Batch No.	ARN25108A	Sampled by	Rakesh
Batch Size	4,940 Vials	Sampled on	03/02/2026
Mfg. Date	01/2026	Date of Testing	04/02/2026
Exp. Date	12/2027	Date of Release	18/02/2026

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 $\pm 10\%$	-2.03% & +1.75%
4.	Average weight	Informative $\pm 2\%$.	855.1 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%	0.42%
	Not more than four such peaks	NMT 0.4%	Not Detected
	Sum of areas of all secondary peaks	NMT 3.5%	0.42%
7.	pH	4.0 to 6.0	5.68
8.	Water	NMT 3.0%w/w	2.66%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 $\geq 10\mu\text{m}$ (ii.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	141/vial 3/vial
10.	Sterility	No microbial growth should be observed.	Complies

Analysis by

NAME: RAMANJEET SINGH

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. 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) IP Lyophilized		500 mg	518.6875 mg	103.74%	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/HS.~~

Analysis by  NAME: RAMANJEET SINGH	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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