



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title : Certificate of Analysis Finished Product

Product Name	CLOCIVIR Injection	A.R. No.	ARN/FP/25/044
Generic Name	Aciclovir Intravenous Infusion IP 250mg	Sampled qty.	45 vials
Batch No.	ARN2543A	Sampled by	Rakesh
Batch Size	20,000 Vials	Sampled on	27/10/2025
Mfg. Date	10/2025	Date of Testing	28/10/2025
Exp. Date	09/2027	Date of Release	11/11/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white, crystalline powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification By UV	A. When examined in the range 230 nm to 360 nm the solution prepared in the Assay shows an absorption maximum at about 255 nm and a broad shoulder at about 274 nm.	Complies
	By TLC	B. In the test of Guanine, the principal spot in the chromatogram obtained with test solution (b) corresponds to that in the chromatogram obtained with reference solution (a).	Complies
	By Chemically	C. It gives reaction (A) of sodium salts.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-3.73% & +2.12%
4.	Average weight	Informative $\pm 2\%$.	300.8 mg
5.	Particulate Matter		
	(A.) Light obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	426/vial 3/vial
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	Complies
6.	Appearance of solution	The solution is not more opalescent than opalescence standard OS2, and not more intensely coloured than reference solution BYSS.	Complies
7.	pH	10.7 to 11.7	11.32

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DEWAN
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8.	Related Substances (By TLC)	Any secondary spot with an R_F value greater than that of the principal spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution (0.5 per cent).	Complies		
9.	Guanine (By TLC)	Any secondary spot corresponding to guanine in the chromatogram obtained with test solution (a) is not more intense than the spot in the chromatogram obtained with reference solution (b) (1.0 per cent).	Complies		
10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 0.174 EU/mg of Aciclovir.	Less than 0.174 EU/mg of Aciclovir.		
12.	Assay: (By UV) Each glass vial Contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Aciclovir Sodium (Lyophilized) Eq. to Aciclovir IP		250 mg	254.82 mg	101.93%	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.

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