



Add Pace To Health

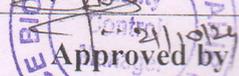
# Pace Biotech

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

## Title : Certificate of Analysis Finished Product

Product Name	CLOCIVIR Infusion	A.R. No.	NB/FP/24/195
Generic Name	Acyclovir Intravenous Infusion IP 250mg	Sampled qty.	45 vials
Batch No.	N24164A	Sampled by	Boby Kumar
Batch Size	7000 Vials	Sampled on	05/10/2024
Mfg. Date	09/2024	Date of Testing	05/10/2024
Exp. Date	08/2026	Date of Release	21/10/2024

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	<p>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.</p> <p>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).</p> <p>C. It gives reaction of Sodium salts.</p>	<p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Uniformity of weight	Average weight $\pm 10\%$	-4.69% & +2.57%
4.	Average weight	Informative.	292.0 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	575/vial 3/vial 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	11.17

Analysis by  Checked by  Approved by 



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8.	Related Substances (By TLC)	Any secondary spot with an R <sub>F</sub> 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).	Not detected		
9.	Guanine	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).	0.24%		
10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT- 0.174 EU/mg of Acyclovir.	Less than- 0.174 EU/mg of Acyclovir.		
12.	Assay : Each glass vial Contains				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Acyclovir Sodium (Lyophilized) Eq. to Acyclovir IP		250 mg	253.99 mg	101.60%	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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