

Pace

Add Pace To Health

Pace Biotech

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

Title

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Certificate of Analysis Finished Product

Product Name	CLOCIVIR 500MG Injection	A.R. No.	NB/FP/24/198
Generic Name	Acyclovir Intravenous Infusion IP 500mg	Sampled qty.	45 vials
Batch No.	N24163A	Sampled by	Rakesh
Batch Size	12,000 Vials	Sampled on	14/10/2024
Mfg. Date	09/2024	Date of Testing	14/10/2024
Exp. Date	08/2026	Date of Release	29/10/2024

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 By HPLC	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. 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). C. It gives reaction of Sodium salts. In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working standard solution	Complies Complies Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.09% & +2.44%
4.	Average weight	Informative.	597.7 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.	1610/vial 6/vial Complies
6.	Appearance of solution	The solution is not more opalescent than opalescence standard OS2, and not more intensely coloured than reference solution BY55.	Complies
7.	pH	10.7 to 11.7	

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Quality Control Manager

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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).	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).	Complies		
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		500 mg	519.83 mg	103.97%	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/USPAHS.

Analysis by	Checked by	Approved by
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