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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**CLOCIVIR 500MG** Injection	**A.R. No.**	NB/FP/23/329
Generic Name	Acyclovir Intravenous Infusion IP 500mg	**Sampled qty.**	45 vials
Batch No.	N23271G	**Sampled by**	Aakash
Batch Size	6613 Vials	**Sampled on**	19/12/2023
Mfg. Date	10/2023	**Date of Testing**	19/12/2023
Exp. Date	09/2025	**Date of Release**	03/01/2024

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	**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.	Complies Complies Complies
3.	Uniformity of weight	Average weight ±10%	-1.83% & +2.82%
4.	Average weight	Informative.	600.1 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	236/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 BYS5.	Complies
7.	pH	10.7 to 11.7	11.63
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

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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	506.25 mg	101.25%	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~~.

Analysis by	**Checked by**	**Approved by**

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager 03/01/24