Pacé
Add Pace To Health

Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	**CLOCIVIR** 500MG Infusion	**A.R. No.**	NB/FP/23/402
Generic Name	Aciclovir Intravenous Infusion IP 500mg	**Sampled qty.**	45 vials
Batch No.	N23342F	**Sampled by**	Vineet
Batch Size	19,500 Vials	**Sampled on**	18/02/2024
Mfg. Date	12/2023	**Date of Testing**	18/02/2024
Exp. Date	11/2025	**Date of Release**	04/03/2024

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%	-1.11% & +1.02%
4.	Average weight	Informative.	593.6 mg
5.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT-6000/vial NMT-600/vial	561/vial 5/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	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	11.47
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

Pace Biotech

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

Title : **Certificate of Analysis Finished Product**

Product Name	**CLOCIVIR** 500MG Infusion	**A.R. No.**	NB/FP/23/402
Generic Name	Aciclovir Intravenous Infusion IP 500mg	**Sampled qty.**	45 vials
Batch No.	N23342F	**Sampled by**	Vineet
Batch Size	19,500 Vials	**Sampled on**	18/02/2024
Mfg. Date	12/2023	**Date of Testing**	18/02/2024
Exp. Date	11/2025	**Date of Release**	04/03/2024

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 Aciclovir.	Less than- 0.174 EU/mg of Aciclovir.

12. Assay :
Each glass vial Contains

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Aciclovir Sodium (Lyophilized) Eq. to Aciclovir IP	500 mg	522.69 mg	104.54%	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~~.

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

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