

Pace Biotech

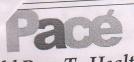
Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title :

Certificate of Analysis Finished Product

Product Name	Clocivir Injection	A.R. No.	NB/FP/23/445
Generic Name	Aciclovir Intravenous Infusion IP 500mg	Sampled qty.	45 vials
Batch No.	N23399A	Sampled by	Arvind
Batch Size	1960 Vials	Sampled on	19/03/2024
Mfg. Date	02/2024	Date of Testing	19/03/2024
Exp. Date	01/2026	Date of Conditionally Release	26/03/2024

S. No.	Tests	Specifications	Observations	
1.	Description A white or almost white, crystalling 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 350 nm exhibit an absorption maximum at about 255 nm and a broad shoulder at about 274 nm.	Complies	
		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	
3.	Uniformity of weight	C. It gives reaction of Sodium salts. Average weight ±10%	-1.46% & +2.40%	
	The second secon	Informative.	593.4 mg	
4.	Average weight	informative.	3)3.4 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.	527/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 BYS5.	Complies	
7.	pH	10.7 to 11.7	11.68	
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).		



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Add Pace To Health | Certificate of Analysis Finished Product

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9.	Guanine	Any secondary s to guanine in obtained with tes more intense the chromatogram	the chromatogi at solution (a) is an the spot in obtained v	am not the vith	Complies
10.	Sterility . Bacterial Endotoxins	reference solutio No microbial gro observed. NMT- 0.174 EU	owth should be		nder process - 0.174 EU/mg of
12.	Assay: Each glass vial Contains	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Lvc	ophilized) to Aciclovir IP	500 mg	500.96 mg	100.19% above is/ is no	95.0% to 105.0% t of the standard Ties/ not complies as

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 Manager