

Title

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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, 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 350 nm exhibit 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 $\pm 10\%$	-1.46% & +2.40%
4.	Average weight	Informative.	593.4 mg
5.	<p>Particulate Matter</p> <p>(a.) Sub-Visible particle count</p> <p>(1.) Particles $\geq 10\mu\text{m}$</p> <p>(2.) Particles $\geq 25\mu\text{m}$</p> <p>(b.) Visual</p>	<p>NMT-6000/vial</p> <p>NMT-600/vial</p> <p>The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.</p>	<p>527/vial</p> <p>3/vial</p> <p>Complies</p>
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	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).	Under process

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

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

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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.	Under process		
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) Eqp. to Aciclovir IP		500 mg	500.96 mg	100.19%	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/HS.

Analysis by 	Checked by 	Approved by  Quality Manager
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