

Title

:

Certificate of Analysis Finished Product

Product Name	Clocivir Injection	A.R. No.	NB/FP/23/425
Generic Name	Aciclovir Intravenous Infusion IP 250mg	Sampled qty.	45 vials
Batch No.	N23426A	Sampled by	Aakash
Batch Size	3360 Vials	Sampled on	05/03/2024
Mfg. Date	02/2024	Date of Testing	05/03/2024
Exp. Date	01/2026	Date of Release	20/03/2024

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 350 nm exhibit a 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 $\pm 10\%$	-2.34% & +2.92%
4.	Average weight	Informative.	296.5 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.	197/vial 1/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	11.45
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
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

Title : Certificate of Analysis Finished Product

Product Name	Clocivir Injection	A.R. No.	NB/FP/23/425
Generic Name	Aciclovir Intravenous Infusion IP 250mg	Sampled qty.	45 vials
Batch No.	N23426A	Sampled by	Aakash
Batch Size	3360 Vials	Sampled on	05/03/2024
Mfg. Date	02/2024	Date of Testing	05/03/2024
Exp. Date	01/2026	Date of Release	20/03/2024

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	250 mg	254.20 mg	101.68%	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/AHS.

Analysis by 	Checked by 	Approved by 
---	--	---

