

Title

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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	<p>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.</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 $\pm 10\%$	-1.83% & +2.82%
4.	Average weight	Informative.	600.1 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.	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 BY55.	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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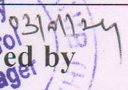
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9.	Guanine	Any secondary spot corresponding to guanine in the chromatogram obtained with test solution (a) is not more intense than the spot in the chromatogram obtained with reference solution (b) (1.0 per cent).	Complies
10.	Sterility	No microbial 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/THS.

Analysis by 	Checked by 	Approved by 
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