

Title

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**Certificate of Analysis Finished Product**

Product Name	CLOCIVIR 250MG Infusion	A.R. No.	NB/FP/24/140
Generic Name	Acyclovir Intravenous Infusion IP 250mg	Sampled qty.	45 vials
Batch No.	N24095A	Sampled by	Vineet
Batch Size	4400 Vials	Sampled on	21/08/2024
Mfg. Date	07/2024	Date of Testing	21/08/2024
Exp. Date	06/2026	Date of Conditionally Release	28/08/2024

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  Under process  Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.91% & +3.11%
4.	Average weight	Informative.	309.3 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.	143/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 BYSS5.	Complies
7.	pH	10.7 to 11.7	11.35

Analysis by

Checked by

Approved by



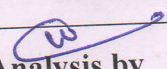
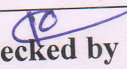
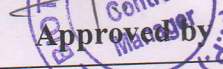


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8.	Related Substances (By TLC)	Any secondary spot with an R <sub>F</sub> value greater than that of the principal spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with reference solution (0.5 per cent).	Under process		
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).	Under process		
10.	Sterility	No microbial growth should be observed.	Under process		
11.	Bacterial Endotoxins	NMT- 0.174 EU/mg of Acyclovir.	Less than- 0.174 EU/mg of Acyclovir.		
12.	Assay : Each glass vial Contains				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>• Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
(Sterile) Acyclovir Sodium (Lyophilized) Eq. to Acyclovir IP		250 mg	261.63 mg	104.65%	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.

 Analysis by	 Checked by	 Approved by
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