

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

| | | | |
|--------------|---|-----------------|--------------|
| Product Name | CLOCIVIR 250 Injection | A.R. No. | NB/FP/24/247 |
| Generic Name | Acyclovir Intravenous Infusion IP 250mg | Sampled qty. | 45 vials |
| Batch No. | N24219F | Sampled by | Rakesh |
| Batch Size | 4933 Vials | Sampled on | 23/11/2024 |
| Mfg. Date | 10/2024 | Date of Testing | 23/11/2024 |
| Exp. Date | 09/2026 | Date of Release | 09/12/2024 |

| 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 $\pm 10\%$ | -1.33% & +0.86% |
| 4. | Average weight | Informative. | 301.4 mg |
| 5. | Particulate Matter | | |
| | (a.) Sub-Visible particle count | | |
| | (1.) Particles $\geq 10\mu\text{m}$ | NMT-6000/vial | 1672/vial |
| | (2.) Particles $\geq 25\mu\text{m}$ | NMT-600/vial | 2/vial |
| | (b.) Visual | The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally. | 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 | 11.68 |

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI

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|---|-------------------------------------|--|--------------------------------------|---------------------|----------------------------|
| 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). | Not detected | | |
| 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). | Not detected | | |
| 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 | | 250 mg | 256.86 mg | 102.74% | 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.

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|--|------------------------------------|---|
| Analysis by NAME: SUFIYAN ANSARI | Checked by NAME: SANDHYA | Approved by NAME: P.N. TRIPATHI |
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