

Certificate of Analysis Finished Product

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|---------------------|-------------------------------|------------------------|--------------|--|
| Title | : | | | |
| Product Name | ARTECAN Injection | A.R. No. | NB/FP/24/262 | |
| Generic Name | Artesunate Injection IP 120mg | Sampled qty. | 45 Vials | |
| Batch No. | N24231C | Sampled by | Boby Kumar | |
| Batch Size | 16,000 Vials | Sampled on | 05/12/2024 | |
| Mfg. Date | 11/2024 | Date of Testing | 05/12/2024 | |
| Exp. Date | 10/2026 | Date of Release | 20/12/2024 | |

| S. No. | Test | Specification | Observation |
|--------|--|--|--|
| 1. | Description | A white or almost white crystalline powder filled in clear glass vial. | A white crystalline powder filled in clear glass vial. |
| 2. | Identification (By IR) | The infrared absorption spectrum is concordant with the spectrum obtained from artesunate RS or with the reference spectrum of artesunate. | Complies |
| 3. | Uniformity of weight | Average weight $\pm 10\%$ | -4.40% & +3.10% |
| 4. | Average weight | Informative. | 119.9 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. | 1309/vial 72/vial Complies |
| 6. | Related Substances (By HPLC w/w) Impurity A Impurity B Impurity C Any other Impurity Total Impurity | Note more than-1.0% Note more than-0.5% Note more than-0.3% Note more than-0.3% Note more than-2.0% | Not detected Not detected Not detected Not detected Not detected |
| 7. | Water (By K.F) | NMT- 0.5% w/w | 0.09%w/w |
| 8. | Sterility | No microbial growth should be observed. | Complies |
| 9. | Bacterial Endotoxins | NMT- 2.5 EU/mg of Artesunate. | Less than- 2.5 EU/mg of Artesunate. |
| 10. | Assay: Each vial Contains : | | |

| Ingredients | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|-------------------------|---------------|-----------|---------------------|----------------------------|
| Artesunate (Sterile) IP | 120 mg | 118.43 mg | 98.69% | 90.0 to 110.0% |

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.

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