



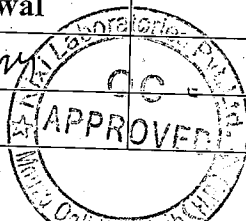
Nixi Laboratories Pvt. Ltd.
VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

| | | | |
|----------------------------|--------------------------------|-----------------------------|-------------------|
| Product Name | Artecan | AR. No. | NL/DI/FG/24/404 |
| Generic Name | Artesunate Injection IP 120 mg | | |
| Mother Batch No. | D24AE006 | Reference | IP |
| Child Batch No. | D24AE006B | Batch Size | 10200 Vials |
| Mfg. Date | 04/2024 | Exp. Date | 03/2026 |
| Specification No. (STS No) | QC/DPI/FG/STS/002-02 | Standard Test Procedure No. | QC/DPI/FG/STP/002 |
| Sample Quantity | 60Vials | Sample Date | 30/05/2024 |
| Release Date | 13/06/2024 | | |

| Sr. No. | Test | Specification | Observation |
|---------|---|---|---|
| 1. | Description | White or almost white crystalline powder filled in clear glass vial, plugged with rubber stopper and sealed with flip off aluminum seal. | White crystalline powder filled in clear glass vial, plugged with grey rubber stopper and sealed with flip off aluminum seal. |
| 2. | Identification: Test A may be omitted if test B, C and D are carried out. Test B, C and D may be omitted if test A is carried out. | | |
| | A. By Infrared Absorption Spectroscopy (IR) | Compare the spectrum with that obtained with Artesunate WS or with the reference spectrum of Artesunate. | Complies |
| | B. By Thin-layer Chromatography (TLC) | Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution. | Complies |
| | C. By Chemical | A light red violet colour is produced. | Complies |
| | D. By Chemical | A reddish-brown colour is produced. | Complies |
| 3. | Clarity of solution | The solid dissolve completely, leaving no visible residue as undissolved matter. The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar | Complies Complies |

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|-----------|-------------|----------------|--------------|
| Name | Akhilak | Ganesh Jaiswal | Aditya Singh |
| Signature | | | |
| Date | 13/06/24 | 13/06/24 | 13/06/24 |





Nixi Laboratories Pvt. Ltd.

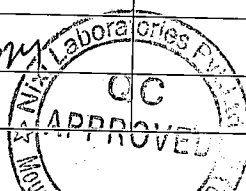
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| | | | |
|-----|--|---|---|
| | | container and examined in the same manner. | |
| 4. | Average filled Weight | 128 mg ± 5% | 127.6 mg |
| 5. | Uniformity of filled Weight | Average filled weight ± 5% | -2.23 to +1.14 % |
| 6. | Particulate matter | | |
| | Visible particles | Should be free from visible particles | Complies |
| | For sub visible particles : (i) Equal to or greater than 10µm (ii) Equal to or greater than 25µm | NMT 6000particles/container NMT 600particles/container | 2174.0 particles/container 5.3 particles/container |
| 7. | Sterility | Should comply the test of sterility | Complies |
| 8. | Bacterial Endotoxins | NMT 2.5 EU /mg of Artesunate. | Complies |
| 9. | Water Content | NMT 0.5% | 0.31 % |
| 10. | Related substances | | |
| | (i) Impurity A | Not more than 1.0% | Not Detected |
| | (ii) Impurity B | Not more than 0.5% | Not Detected |
| | (iii) Impurity C | Not more than 0.3% | 0.10% |
| | (iv) Any other secondary Imp | Not more than 0.3% | Not Detected |
| | (v) Sum of all impurities | Not more than 2.0% | Not Detected |
| 11. | Assay: Each Vial Contains: Artesunate (Sterile) IP 120 mg | 108.0 mg to 132.0 mg (90.0 % to 110.0 %) | 126.90 mg (105.75 %) |

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|-----------|-------------|----------------|--------------|
| Name | Akhilak | Ganesh Jaiswal | Aditya Singh |
| Signature | | | |
| Date | 13/06/2024 | 13/06/2024 | 13/06/2024 |





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RESULT: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No- QC/DPI/FG/STS/002-02.

Conclusion : In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|-----------|-------------|----------------|--------------|
| Name | Akhilak | Ganesh Jaiswal | Aditya Singh |
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| Date | 13/06/24 | 13/06/24 | 13/06/24 |

