

Nixi Laboratories Pvt. Ltd.

VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

| Product Name Artecon | | | | |
|----------------------|-------------------------|---------------|-------------------|--|
| Product Name | Artecan | AR. No. | | |
| Generic Name | Artesunate Injection IP | AR. 110. | NL/DI/FG/24/408 | |
| Mother Batch No. | D24AD009 | D.C. | | |
| Child Batch No. | D24AD009B | Reference | IP | |
| Mfg. Date | 04/2024 | Batch Size | 10200 Vials | |
| Specification No. | 04/2024 | Exp. Date | 03/2026 | |
| (STS No) | QC/DPI/FG/STS/002-01 | Standard Test | OC/DDITE CO | |
| Sample Quantity | 60 Vials | Procedure No. | QC/DPI/FG/STP/002 | |
| Release Date | | Sample Date | 29/05/2024 | |
| recrease Date | 12/06/2024 | | | |

| Sr. No. | | Test | | Specification | | |
|---|--|----------------------|-------------------------|--|------------------------------------|--|
| 1. | Desci | ription | W | ite or almost white crystalline | Observation | |
| | | • | nor | vder filled in clear glass vial, | White crystalline powder filled in | |
| | | | nlu | grad with mall | clear glass vial, plugged with | |
| | | | pru | gged with rubber stopper and | rubber stopper and sealed with | |
| | | | | led with flip off aluminum seal. | flip off aluminum seal. | |
| 2. | Identi | ification: Test A ma | y be on | nitted if test B. C and D are car | ried out Tort D. C. 1.D. | |
| | 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. | | | | | |
| | - TD | T 0 | · · | <u> </u> | | |
| | | Infrared | Con | apare the spectrum with that | Complies | |
| | | ption Spectroscopy | obta | ined with Artesunate WS or | · | |
| | (IR) | | with | the reference spectrum of | | |
| | | | Arte | sunate. | s, | |
| _ | | • | | • | | |
| , | B. By | Thin-layer | Any | secondary spot in the | NA | |
| | | natography (TLC) | chro | matogram obtained with the | | |
| | | 8 - I-J (120) | test s | solution is not more intense | | |
| | | | than | the spot in the chromatogram | | |
| | | | obtai | ned with the reference | | |
| | | | solut | and the second s | * | |
| | | | Solut | ion. | | |
| | C. By (| Chemical | A lig | ht red violet colour is | Complian | |
| | | | produ | iced. | Complies | |
| | D. By (| Chemical | _ | ddish-brown colour is | | |
| | | | | uced. | Complies | |
| 3. | Clarit | of ~_1 | | | - July 100 | |
| <i>J</i> . | Сіагну | of solution | The s | olid dissolve completely, | Complies | |
| | | | leavir | ng no visible residue as | a - | |
|] , | | | undis | solved matter. | | |
| _ | | • | The a | angtituted initiati | Complies | |
| <u>-</u> | | ANALYSED B | | onstituted injection is not | | |
| ame | · · · | | | CHECKED BY | APPROVED BY | |
| ame Tarun Kumar gnature ate 72/4/29 | | r. | Ganesh jaiswal | Aditya Singh | | |
| | | | - au e 6/2021/ 3/001310 | | | |
| | | | 1M 60/100 | Cam arm | | |
| ormat No. | : SOP/C | C/013/F03-03 | · · | - ADDD | and so lan | |
| | | (=. 0.1011.00=00 | | MAPPRE | Page 1 of 3 | |



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

| Product Name CERTIFICATE OF ANALYSIS FINISHED PRODUCTS | | | | |
|--|-------------------------|---------------|--------------------|--|
| Product Name | Artecan | AR. No. | | |
| Generic Name | Artesunate Injection IP | AK. 110. | NL/DI/FG/24/408 | |
| Mother Batch No. | D24AD009 | Reference | * | |
| Child Batch No. | D24AD009B | Batch Size | IP | |
| Mfg. Date | 04/2024 | | 10200 Vials | |
| Specification No. | | Exp. Date | 03/2026 | |
| (STS No) | QC/DPI/FG/STS/002-01 | Standard Test | QC/DPI/FG/STP/002 | |
| Sample Quantity | 60 Vials | Procedure No. | QC/DT1/T-G/STP/002 | |
| Release Date | 12/06/2024 | Sample Date | 29/05/2024 | |

| | | giorgia di 1 | |
|----------|------------------------------------|---|---------------------------|
| | | significantly less clear than an | |
| | | equal volume of the diluent or of | |
| | • | water for injections contained in a similar container and examined in | |
| | | the same manner. | |
| 4. | Average filled Weight | $64 \text{ mg} \pm 5\%$ | 62.9 mg |
| 5. | Uniformity of filled | Average filled weight ± 5% | |
| <u> </u> | Weight | Two tage inned weight ± 5% | -2.96% to +3.40% |
| 6. | Particulate matter | | |
| | Visible particles: | Should be free from visible | Complies |
| | | particles | Compiles |
| | For sub visible particles: | | |
| .* | (i) Equal to or greater than 10μm | NMT 6000particles/container | 196.7 particles/container |
| ÷ | (ii) Equal to or greater than 25µm | NMT 600particles/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% | 0.16% |
| 10. | Related substances | • | ů. |
| | (i) Impurit | | |
| | (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% | 0.065% |
| | (iv) Any other secondary | Not more than 0.3% | Not Detected |
| | Imp | , | |
| | (v) Sum of all impurities | Not more than 2.0% | Not Detected |

| | | | • |
|-------------------|---------------|----------------|--------------|
| | ANALYSED BY | CHECKED BY | APPROVED BY |
| Name | Tarun Kumar | Ganesh jaiswal | A 3:4 . G: 1 |
| Signature | · 8 | au hoise | |
| Date | 12/16/24 | MOLINA C | C VO WING IM |
| Format No.: SOP/O | QC/013/F03-03 | | Poss 2 - 62 |

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VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

| Product Name Artegory Artegory | | | | |
|--------------------------------|-------------------------|--------------------------------|-------------------|--|
| Product Name | Artecan | AD No | | |
| Generic Name | Artesunate Injection IP | AR. No. | NL/DI/FG/24/408 | |
| Mother Batch No. | D24AD009 | TD 6 | | |
| Child Batch No. | D24AD009B | Reference | IP | |
| Mfg. Date | 04/2024 | Batch Size | 10200 Vials | |
| Specification No. | 04/2024 | Exp. Date | 03/2026 | |
| (STS No) | QC/DPI/FG/STS/002-01 | Standard Test Procedure No. | QC/DPI/FG/STP/002 | |
| Sample Quantity | 60 Vials | Sample Date | | |
| Release Date | 12/06/2024 | Sample Date | 29/05/2024 | |

| 11. | Assay: | | <i>i</i> 4 | |
|----------|------------|---|------------------------|---|
| | | 54.00 mg to 66.00 mg (90.00 % to 110.00 %) | 63.38 mg (105.63 %) | |
| PETIT T. | The change | | | - |

RESULT: The above sample COMPLIES/DOES NOT COMPLY as per Specification No-QC/DPI/FG/STS/002-01.

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

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|-------------------|---------------|----------------|--------------|
| Vame | Tarun Kumar | Ganesh jaiswal | Aditya Singh |
| lignature | R | Say 300 | Autya Singh |
| ate | 12/16/24 | MOC/ VEKA | C Modelm |
| Format No.: SOP/(| QC/013/F03-03 | | Man |

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