**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/337

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| **PRODUCT** | ARTESIANE® 20 INJECTION | | **REF. NO: NDQD201609146** |
| **DATE RECEIVED:** 29.09.2016 | **LABEL CLAIM:** | Composition: Artemether 20 mg Solvent: Fractionated coconut oil to 1 mL. | |
| **BATCH NO.:** 50108 | **PRESENTATION:** | Clear, colourless liquid for intramuscular injection contained in transparent 1 mL glass ampoules packed in a plastic rack carrying 10 ampoules in a printed unit box. | |
| **MFG. DATE:** Mar. 2015 | **MANUFACTURER:** | ROTEXMEDICA GmbH | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | Bunsenstrasse 4, 22946 Trittau, GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique, P. O. Box 10397 - 00400, Nairobi, Kenya. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Direct Inoculation | BP 2016 Vol. V Appendix XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | International Pharmacopoeia 5th Edition, 2015 | NMT 1.56 IU/mg | 6.64E-05 EU/mg | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App V L | - | 3.93 |  |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 10.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | International Pharmacopoeia 5th Edition, 2015 | 95.0 - 105.0% | 103.8% (RSD=1.2%; n=9) | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | DUNCAN OLUOCH | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | ERIC NGAMAU | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-18-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-30-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 12-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-14-2016 |