**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/106

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| **PRODUCT** | E MAL(TM)-225 INJECTION | | **REF. NO: NDQD201507039** |
| **DATE RECEIVED:** 30.07.2015 | **LABEL CLAIM:** | Each mL contains (use the right symbols) Arteether 75 mg. | |
| **BATCH NO.:** EMC501 | **PRESENTATION:** | Straw coloured oily solution, contained in a 3 mL amber coloured glass ampoule, packed on a plastic rack of 3 ampoules in a unit box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | THEMIS Medicare Limited. | |
| **EXP. DATE:**  Dec. 2017 | **ADDRESS:** | Sector 6A,Plot No.16,17 and 18,IIE, SIDCUL, Haridwar - 249 403, Uttarakhand, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd P. O. Box 42569-00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No Microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | BP 2016 Vol. V App. XIV C | NMT 2 EU/mg | 1.3 X 10-7 EU/mg | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the component peak in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 3.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | 91.9% (RSD = 0.4% ; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 26-08-2015 |
| **ANALYST:** | DR. L. WANGANARI | .......................................................... | DATE: 10-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 14-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |