**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-2016/257

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| **PRODUCT** | Diclopar Injection | | REF. NO: NDQD201507038 |
| **DATE RECEIVED:** 30.07.2015 | **LABEL CLAIM:** | Each mL contains: Diclofenac Sodium B.P. 75 mg, Benzyl Alcohol B.P. 2% v/v & Water for Injection B.P. Q.S. | |
| **BATCH NO.:** ADL428 | **PRESENTATION:** | Clear colourless solution for intravenous and intramuscular administration contained in a 1 mL clear colourless glass ampoule, packed on a plastic rack of 5 ampoules in a unit box | |
| **MGF. DATE:** Jun.2014 | **MANUFACTURER:** | THEMIS Medicare Limited. | |
| **EXP. DATE:**  May.2016 | **ADDRESS:** | Sector 6A, Plot No.16, 17 and 18,IIE, SIDCUL, Haridwar-249 403, Uttarakhand, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd Box 42569-00100, Nairobi | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 vo V Appendix XVI A | No microbial growth | No Microbial Growth | **COMPLIES** |
| **Identification** | HPLC | Maunfacturer's 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 10.0 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations. | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Maunfacturer's In- House Method | NTM 2.33 EU/mg | 6.35 \* 10-5 EU/mg | **COMPLIES** |
| **Assay** | HPLC | Maunfacturer's In- House Method | 95.0-105.0 | 103.3% (RSD = 0.3% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | MR. N. ERIC |  | DATE:08-09-2015 |
| ANALYST: | MR. D. MOENGA |  | DATE:10-11-2015 |
| REVIEWER: | DR. E. TANUI |  | DATE:09-09-2015 |
| REVIEWER: | DR. W. GEORGE |  | DATE:13-11-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-21-2015 |
| ANALYST: | ERIC NGAMAU |  | DATE:12-22-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-01-2016 |