**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | DICLOPAR Gel | | REF. NO: NDQD201507037 |
| **DATE RECEIVED:** 30.07.2015 | **LABEL CLAIM:** | Each gram contains: Diclofenac Diethylamine BP 1.16% w/w Equivalent to Diclofenac Sodium BP 1% w/w & gel base q.s. | |
| **BATCH NO.:** INC402 | **PRESENTATION:** | clear transluscent gel for topical application contained in a 30 g white plastic tube in a unit box. | |
| **MGF. DATE:** Jul.2014 | **MANUFACTURER:** | THEMIS Medicare Limited. | |
| **EXP. DATE:** Jun.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:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count Method | BP 2016 Vol. V App. XVI B | Total Aerobic Microbiol Count(TAMC) NMT 200 CFU/g Total Combined Yeasts/Moulds Count (TYMC) NMT 20 CFU/g | (TAMC)<200CFU/g (TYMC)<20CFU/g | **COMPLIES** |
| **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 8.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | BP 2016 VOL III Pg 460 | 95.0-105.0% | 96.9% (RSD = 0.5%, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | MANUFACTURER'S In- House Method | 7.2-7.8 | 7.3 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:17-08-2015 |
| ANALYST: | MR. D. MOENGA |  | DATE:23-11-2015 |
| REVIEWER: | DR. N. MWAURA |  | DATE:25-11-2015 |
| REVIEWER: | DR. E. TANUI |  | DATE:21-08-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-21-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-12-2016 |