**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | Diclofenac Sodium Injection | | REF. NO: NDQD201507032 |
| **DATE RECEIVED:** 21.07.2015 | **LABEL CLAIM:** | Each mL contains: Diclofenac Sodium B.P. 25 mg. Benzly Alcohol B.P. 4.0 %v/v & Water for Injection B.P. q.s. | |
| **BATCH NO.:** FEDSI-002 | **PRESENTATION:** | Clear colourless solution in a 3 mL colourless glass ampoule, packed in a blister strip of 10 ampoules in a unit box. | |
| **MGF. DATE:** Jan.2015 | **MANUFACTURER:** | LABORATE Pharmaceuticals India Ltd. | |
| **EXP. DATE:** Dec.2017 | **ADDRESS:** | Rajban Road,Paonta Sahib, H.O.:E-11,INDL.AREA,PANIPAT-132 103, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. BOX 47715-00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2012 Vol. V App. XVI A. | No Microbial Growth | No Microbial Growth | **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 7.3 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | HPLC | Adopted In- House Method | 95.0 - 105.0% | 100.9% (RSD = 0.4% ; n = 9) | **COMPLIES** |
| **Acidity/Alkalinity** | HPLC | Adopted In- House Method | 8.2-9.0 | 8.5 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:20-08-2015 |
| ANALYST: | DR. L. WANGARI |  | DATE:02-12-2015 |
| REVIEWER: | DR. E. TANUI |  | DATE:21-08-2015 |
| REVIEWER: | DR. G. WANGANGA |  | DATE:09-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-21-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-12-2016 |