**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/97

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| **PRODUCT** | KOCEF-1000 INJECTION | | **REF. NO: NDQB2016061174** |
| **DATE RECEIVED:** 09-06-2016 | **LABEL CLAIM:** | Each vial contains: Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone (Anhydrous) 1000 mg. | |
| **BATCH NO.:** Powder:LJ87015006 Diluent: 7503739 | **PRESENTATION:** | Off white coloured, free flowing powder for intramuscular or intravenous administration contained in a clear colourless glass vial fitted with a metallic cap and a blue plastic flip off cap, packed along with sterile water for injection in a 10 mL plastic ampoule on a plastic rack in a unit box. | |
| **MFG. DATE:** Powder: Sep. 2015 Diluent: Sep. 2015 | **MANUFACTURER:** | KOPRAN Limited. | |
| **EXP. DATE:**  Powder: Aug. 2018 Diluent: Aug. 2020 | **ADDRESS:** | Village Savroli, Tal. Khalapur, Dist. Raigad - 410 202, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, Kenya. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 vial deviate by more than 10% from the mean vial weight | None Deviates | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP Vol V 2016 Appendix XVI A | Powder and Diluent No Microbial Growth | Powder and Diluent No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 Page 2705 | Powder Less than 0.2 EU/mg | 1.0 — 10-5 EU/mg | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 NF 33 Page 5806 | Diluent Less than 0.25 EU/mL | 2.7 — 10-6 EU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2705 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 3.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** |  | USP 38 NF 33 Page 2705 | 6.0 - 8.0 | 6.7 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2705 | 90.0 - 115.0% | 104.1% (RSD = 1.9% ; n = 7) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 07-19-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |