**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/258

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| **PRODUCT** | MYDAWA CEFUROXIME 250 ORAL SUSPENSION | | **REF. NO: NDQD201607030** |
| **DATE RECEIVED:** 21.07.2016 | **LABEL CLAIM:** | Each 5 mL of reconstituted suspension contains: Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg. | |
| **BATCH NO.:** FK182 | **PRESENTATION:** | Pink coloured powder for reconstitution into suspension for oral administration, contained in a 50 mL translucent plastic bottle, packed along with a 10 mL plastic graduated measuring cup in a printed box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | FINECURE Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | Shimla Pistaur, Malsa Road, Kichha, Udham Singh Nagar, Uttarakhand - 263148, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ION Kenya, Landmark Plaza, Arwings Khodek, Road, P. O. Box 46986-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU/mL |  |
| **Identification** | HPLC | USP 38 NF 33 Page 2707 | RT of the major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 13.3 & 15.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2707 | 3.5 - 7.0 | 4.5 | **COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 2707 | 90.0 - 110.0 % | DAY 1 101.8% (RSD=1.6%; n=6) | **COMPLIES** |
| **Assay** | HPLC |  |  | DAY 7 97.4% (RSD=0.4; n=6) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 03-11-2016 |
| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 03-11-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 03-11-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 03-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-07-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-16-2016 |