**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/78

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| **PRODUCT** | MYDAWA CEFUROXIME AXETIL TABLETS USP 250 mg | | **REF. NO: NDQD201607013** |
| **DATE RECEIVED:** 2016-07-05 | **LABEL CLAIM:** | Each film coated tablet contains Cefuroxime axetil USP equivalent to Cefuroxime 250 mg | |
| **BATCH NO.:** 78150023 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, plain on both faces, packed in an aluminium blister strip of 10 tablets in a unit box. | |
| **MFG. DATE:** Oct. 2015 | **MANUFACTURER:** | STERIL - GENE Life Sciences (P) Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | No. 45, Mangalam Main Road, Mangalam Village, Villanur Commune, Puducherry - 605110, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ION Kenya, Landmark Plaza, Arwings Khodek, Road, P. O. Box 46986-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | One Deviates (-6%) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2708 | RT of the Major Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 15.8 and 18.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2708 | After 15 Mins No tablet is less than 60% | Average = 74% Range | **COMPLIES** |
| **Dissolution** |  |  | After 45 Mins No tablet is less than 80% | 70 - 77% (RSD=3.4%, n=6) |  |
| **Dissolution** |  |  |  | Average = 83% Range |  |
| **Dissolution** |  |  |  | 82 - 83% (RSD=0.8%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 98.7% (RSD=1.1%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 26/08/12-2016 |
| **REVIEWER** | DR. M.KWENA | .......................................................... | DATE: 26/08/2016 |
| **REVIEWER** | DR.E.MBAE | .......................................................... | DATE: 26/08/2016 |
| **DIRECTOR** | DR.H.K.CHEPKWONY | .......................................................... | DATE: 26/08/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |