**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/530

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| **PRODUCT** | KEFUROX 250 TABLETS | | REF. NO: NDQA201509332 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg | |
| **BATCH NO.:** D282 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, packed in an aluminium foil blister of 10 tablets in a unit box. | |
| **MGF. DATE:** Oct. 2014 | **MANUFACTURER:** | FLAMINGO Pharmaceuticals Limited. | |
| **EXP. DATE:**  Sep. 2016 | **ADDRESS:** | Factory: Rabale, Navi Mumbai 400 701, Office: P.O. Box No. 27257, Mumbai 400 701, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 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 tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2708 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | uper-imposable peaks at RT 14.6 and 17.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80% [n=6] | 77% (RSD=3.3%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80% [n=6] | 98% (RSD=6.0%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 100.0%, (RSD=0.6%, n=6) | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-02-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:01-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-20-2016 |