**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/532

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| **PRODUCT** | CEUROX - 250 TABLETS | | REF. NO: NDQA201509330 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains Cefuroxime 250mg (as Cefuroxime Axetil USP) | |
| **BATCH NO.:** B40030 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed '250' on one face and plain on the other, packed in an aluminium foil blister of 10 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2014 | **MANUFACTURER:** | MEDLEY Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jan. 2016 | **ADDRESS:** | 10 & 11, Zari Causeway Rd, Kachigam, Daman, Regd. Office: Medley House, D2, MIDC Area, Andheri (East), Mumbai - 400 093, 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 | Super-imposable peaks at RT 14.6 and 17.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80.0% [n=6] | 76% (RSD=6.7%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80.0% [n=6] | 95% (RSD=8.9%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 99.5% (RSD=0.5%, n=9) | **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 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-20-2016 |