**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** can/2015-16/550

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| **PRODUCT** | CEFUXIME 250 TABLETS | | **REF. NO: NDQA201509329** |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each uncoated tablet contains Cefuroxime Axetil Ph.Eur equivalent to Cefuroxime 250 mg. | |
| **BATCH NO.:** OUATA4011A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'A 33' on one face and plain on the other, packed in an aluminium blister strip of 10 tablets in a unit box. | |
| **MGF. DATE:** Jan. 2014 | **MANUFACTURER:** | AUROBINDO Pharma LImited. | |
| **EXP. DATE:**  Dec. 2016 | **ADDRESS:** | Unit VI, Survey No. 329/39 & 329/47,Chitkul (V), Patancheru Mandal, Medak District,(A.P.), 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 the mean tablets 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 55.0% [n=6] | 89% (n=6; RSD=5.0%) | **COMPLIES** |
| **Dissolution** |  |  | 45 min run No tablet less than 80.0% [n=6] | 92% (n=6; RSD=3.4%) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 94.6% (RSD=1.8%, n=9) | **COMPLIES** |

**CONCLUSION:** The sample 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: 18-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 04-12-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 04-19-2016 |