**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/533

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| **PRODUCT** | AIVCEF-500 TABLETS | | REF. NO: NDQD201512619 |
| **DATE RECEIVED:** 08.12.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Cefuroxime Axetil (Amorphous) USP eq. to Cefuroxime 500 mg | |
| **BATCH NO.:** TCAQ5015F | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in an aluminium foil blister of 10 tablets in a unit box. | |
| **MGF. DATE:** Aug. 2015 | **MANUFACTURER:** | ASSOCIATED Biotech. | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | Village Kishanpura, Guru Majra Road, Nalagarh Road, Baddi, Distt. Solan, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Aiveen (K) LTD P.O. BOX 41601-00100 NAIROBI | |
|  | **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 13.1 and 15.1 -/+ 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% [n=6] | 81% (RSD=3.6%, 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% [n=6] | 98% (RSD=4.1%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 95.5% (RSD=0.4%, 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 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-20-2016 |