**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/108

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| **PRODUCT** | AIVCLAV- 1000 TABLETS | | **REF. NO: NDQD201512620** |
| **DATE RECEIVED:** 08.12.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate USP equivalent to Amoxicillin 875 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic acid 125 mg | |
| **BATCH NO.:** ET15E009 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced, sharp edged tablets, single scored on one face and plain on the other, packed in an aluminium foil strip of 7 tablets and 2 such strips in a unit box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | MEDICEF Pharma | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | # 28, Phase-I EPIP Jharmajri, Baddi, Distt. Solan (H.P.), 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 2227 | RT of the component peaks in the assay sample preparation correspond to those in the standard preparation | Super-imposable peaks at RT 3.5 and 5.2-/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | Amoxicillin No tablet less than 90% | Amoxicillin Average = 96% Range | **COMPLIES** |
| **Dissolution** |  |  | Clavulanic Acid No tablet less than 85% (n=6) | 94 - 100% (RSD=2.1%, n=6) |  |
| **Dissolution** |  |  |  | Clavulanic Acid Average = 106% Range |  |
| **Dissolution** |  |  |  | 104 - 109% (RSD=1.6%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 98.3% (RSD=0.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic acid 103.0% (RSD=0.2%, n=9) |  |

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

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 22-08-2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 22-08-2016 |