**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/526

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| **PRODUCT** | AIVCLAV-375 TABLETS | | REF. NO: NDQD201512613 |
| **DATE RECEIVED:** 08.12.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate USP equivalent to Amoxicillin 250 mg, Diluted Potassium Clavulanate BP equivalent to Clavulanic acid 125 mg and Excipients q.s. | |
| **BATCH NO.:** ET15B003 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, plain on both faces, packed in an aluminium foil-blister strip of 7 tablets and 2 such strips in a unit box. | |
| **MGF. 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 assay standard preparation | Super-imposable peaks at RT; 3.9 & 5.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90%[n=6] No tablet less than 85% [n=6] | Amoxicillin; 98.7%, (RSD=3.1%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90%[n=6] No tablet less than 85% [n=6] | Clavulanic Acid; 93.0% (RSD=1.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin; 99.6%, (RSD=0.8%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Clavulanic Acid; 97.6% (RSD=0.5%; n=9, | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:22-03-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:22-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-24-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-13-2016 |