**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/179

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| **PRODUCT** | AIVCLAV - 228.5 FOR ORAL SUSPENSION | | **REF. NO: NDQD201512621** |
| **DATE RECEIVED:** 08-12-2015 | **LABEL CLAIM:** | Each 5 mL of the reconstituted suspension contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 200 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 28.5 mg. | |
| **BATCH NO.:** ED 15 J 007 | **PRESENTATION:** | Off white coloured, free flowing, powder for reconstitution into oral suspension contained in a 100 mL amber coloured glass bottle and supplied packed with a 10 mL graduated clear plastic measuring cap in a printed 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, KENYA. | |
| - | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/g Total Combined Yeast/Moulds Counts (TYMC) NMT 20 CFU/g | TAMC < 10 CFU/g | **COMPLIES** |
| **Microbial Load** |  |  |  | TYMC < 10 CFU/g | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 page 2226 | 3.8 - 6.6 | 6.1 | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 2226 | RT of the Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 3.8 & 5.9 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 2226 | 90.0 - 120.0% | Amoxicillin Day 1 115.8% (RSD=1.3%; n=9) Day 7 110.0% (RSD=0.7%; n=9) | **COMPLIES** |
| **Assay** |  |  | 90.0 - 125.0% | Clavulanic Acid Day 1 124.6% (RSD=0.5%; n=9) Day 7 102.4% (RSD=0.4%; n=9) |  |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 12-17-2015 |
| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 12-21-2015 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 04-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |