**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/849

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| **PRODUCT** | ZYCLAVE 625 TABLETS | | **REF. NO: NDQA201509364** |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate USP equivalent to Amoxicillin 500 mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 125 mg. | |
| **BATCH NO.:** AB-1402 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex-faced, sharp edged tablets,single scored on one face and plain on the other, packed in a blister strip of 10 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Jul. 2014 | **MANUFACTURER:** | AUGMENT Remedies. | |
| **EXP. DATE:**  Jun. 2016 | **ADDRESS:** | 21, Nalanda Complex, Premchand Nagar Road, Vastrapur, Ahmedabad - 380 015, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOCLAV/2/13/03/2015/00232 | **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% | Average 88% Range | **COMPLIES** |
| **Dissolution** |  |  | Clavulanic Acid No tablet less than 85% (n=6) | 85% - 92% (RSD=3.6%, n=6) |  |
| **Dissolution** |  |  |  | Average 102% Range |  |
| **Dissolution** |  |  |  | 91% - 114% (RSD=7.4% n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 97.7% (RSD=1.2%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic acid 93.6% (RSD=0.7%, n=9) | **COMPLIES** |

**CONCLUSION:** The sample was found not to comply with the specifications for the stage one dissolution test for amoxicillin and there were insufficient samples to carry out a stage two dissolution test performed. However from the stage one data, there is a high probability that the sample will comply with the stage two test.

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 5-6-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 14-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-20-2016 |