**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/852

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| **PRODUCT** | CLAVAM 625 TABLETS | | **REF. NO: NDQA201509361** |
| **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.:** 4150333 | **PRESENTATION:** | Off white coloured, oval shaped, biconvex-faced, sharp edged tablets, plain on both faces, packed in an aluminium foil blister strip of 10 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | ALKEM Laboratories Ltd. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | 167/1, Village Dabhel, Daman - 396 210, H.O. Alkem House, Senapati Bapat Marg,Lower Parel, Mumbai - 400 013 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOCLAV/03/15/03/2015/00195 | **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 3.9 and RT 5.7 -/+ 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 94.3% (RSD=0.6%, n=6) | **COMPLIES** |
| **Dissolution** |  |  | Clavulanic Acid No tablet less than 85% (n=6) | Clavulanic acid 101.9% (RSD=1.6% n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 105.5% (RSD=0.7%, n=9 | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic acid 93.5% (RSD=1.2%, n=6) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 29-02-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 16-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-20-2016 |