**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/112

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| **PRODUCT** | ACINET 625 MG TABLETS | | **REF. NO: NDQA201509359** |
| **DATE RECEIVED:** 2015-09-29 | **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.:** 4150493 | **PRESENTATION:** | Off white coloured, ovoid shaped, biconvex faced tablets, plain on both faces, 10 tablets packed in blister packs, one such blister contained in a unit box. | |
| **MFG. DATE:** Oct. 2014 | **MANUFACTURER:** | ALKEM Laboratories Ltd. | |
| **EXP. DATE:**  Sep. 2016 | **ADDRESS:** | 167/1, Village Dabhel, Daman - 396 210, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P.O. Box 27663-00506 Nairobi, KENYA. | |
| AMOCLAV/07/12/03/2015/00212 | **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 weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2227 | RT of the Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 3.5 & 5.2 -/+ 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% | Amoxicillin Average = 87% Range | **DOES NOT COMPLY** |
| **Dissolution** |  |  | No Tablet Less Than 85% | 81 - 93%; (2 Tablets less than 90%; RSD=5.0%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Clavulanic acid Average = 94% Range |  |
| **Dissolution** |  |  |  | 88 - 97% (RSD=3.3%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 105.9% (RSD=1.1%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic Acid 95.4% (RSD=1.1%, n=9) |  |

**CONCLUSION:** The product does not comply with the specification for stage 1 dissolution of Amoxicillin. However, there were insufficient samples to perform a stage 2 test.

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 12-21-2015 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 23-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |