**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/500

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| **PRODUCT** | RAPICLAV-625 TABLETS | | REF. NO: NDQD201509365 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Amoxicillin Trihydrate U.S.P. equivalent to Amoxicillin 500 mg, Potassium Clavulanate equivalent to Clavulanic Acid 125 mg. | |
| **BATCH NO.:** BWZ154006 | **PRESENTATION:** | Off White coloured, caplet shaped, biconvex faced tablets, embossed 'R625' on one face and plain on the other, packed in an aluminium foil strip of 2 tablets and 5 such strips packed in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | IPCA Laboratories Ltd. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | Plot No. 69-72 (B), Sector II, KSEZ, Gandhidham ÃƒÆ’Ã‚Â¢ÃƒÂ¢Ã¢â‚¬Å¡Ã‚Â¬ÃƒÂ¢Ã¢â€šÂ¬Ã…â€œ 370 230, Regd. Off.: 48, Kandivli Ind. Estate, Mumbai 400 067, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOXCLAV/08/12/2015/00161 | **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 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90.0% [n=6] No tablet less than 85.0% [n=6] | Amoxicillin; 91.9% (RSD=1.1%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90.0% [n=6] No tablet less than 85.0% [n=6] | Clavulanic Acid; 91.7% (RSD=2.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin; 98.5% (RSD=1.6%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Clavulanic Acid; 98.0% (RSD=1.3%; 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 |