**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/502

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| **PRODUCT** | KOACT 625 TABLETS | | REF. NO: NDQA201509360 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film - coated tablet contains; Amoxicillin Trihydrate Ph. Eur. equivalent to Amoxicillin 500 mg and Potassium Clavulanate Ph. Eur. equivalent to Clavulanic Acid 125 mg. | |
| **BATCH NO.:** NX5014006-A | **PRESENTATION:** | Off-white coloured, ovoid shaped, biconvex faced tablets, embossed '64' on one face and 'A' on the other, packed in an aluminium blister of 5 tablets and 3 such strips packed in a unit box. | |
| **MGF. DATE:** Apr.2014 | **MANUFACTURER:** | AUROBINDO Pharma Ltd. | |
| **EXP. DATE:**  Mar.2016 | **ADDRESS:** | Unit XII, Survey No. 314, Bachupally (Village), Quthubullapur Mandal, Ranga Reddy District, (A.P.), Regd.Office: Plot No.; 2, Maitrivihar, Ameerpet, Hyderabad-500 038, (A.P.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOCLAV/09/12.03.2015/318 | **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; 99.6% (RSD=1.4%; 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; 85.1% (RSD=2.3%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin; 112.4% (RSD=1.6%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Clavulanic Acid; 94.2% (RSD=0.9%; 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 |