**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | KOACT 625 TABLETS | | REF. NO: NDQA201510409 |
| **DATE RECEIVED:** 01.10.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Amoxicillin Trihydrate Ph. Eur. equivalent to Amoxicillin 500 mg, Potassium Clavulanate Ph. Eur. equivalent to Clavulanic Acid 125 mg. | |
| **BATCH NO.:** NX5014013-C | **PRESENTATION:** | White coloured, ovoid shaped, biconvex faced tablets, embossed '64' on one face and 'A' on the opposite, packed in aluminium foil blister strips of five (5) tablets each contained in a unit box carrying 3 such strips. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:** May 2016 | **ADDRESS:** | Unit XII, Survey No. 313, Bachupally (Village), Quthubullapur Mandal, Ranga Reddy District (A.P.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| PV/15/63 | **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 Vol. 2 Page 2226 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT ; 3.8 and 6.0 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | Clavulanic acid: No Tablet Less than 85% [n=6]: | Clavulanic Acid | **DOES NOT COMPLY** |
| **Dissolution** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | Clavulanic acid: No Tablet Less than 85% [n=6]: | 91.9% (RSD = 1.4%; n=6) | **DOES NOT COMPLY** |
| **Dissolution** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | Clavulanic acid: No Tablet Less than 85% [n=6]: |  | **DOES NOT COMPLY** |
| **Dissolution** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | Clavulanic acid: No Tablet Less than 85% [n=6]: | Amoxicillin 80.9% (RSD = 2.5%; n=12) | **DOES NOT COMPLY** |
| **Assay** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | 90.0 - 120.0% | Clavulanic Acid | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | 90.0 - 120.0% | 93.2% (RSD = 1.7%; n=9) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | 90.0 - 120.0% | Amoxicillin | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol. 2 Page 2226 | 90.0 - 120.0% | 94.4% (RSD = 0.2%; n=6) | **COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:15-01-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:15-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-21-2016 |