**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/6

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| **PRODUCT** | KOACT 312.50 POWDER for ORAL SUSPENSION | | **REF. NO: NDQB201603801** |
| **DATE RECEIVED:** 2016-03-15 | **LABEL CLAIM:** | Each 5 mL spoonful (After reconstitution) contains: Amoxicillin Trihydrate Ph. Eur. equivalent to Amoxicillin 250 mg and Potassium Clavulanate, diluted Ph. Eur. equivalent to Clavulanic Acid 62.50 mg. | |
| **BATCH NO.:** CI2515037 - A | **PRESENTATION:** | Off white powder for oral administration contained in a 100 mL transluscent plastic bottle and supplied along with a 10 mL graduated clear plastic measuring cap in a unit box. | |
| **MGF. DATE:** Aug. 2015 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  Jan. 2017 | **ADDRESS:** | Unit-XII, Survey No. 314, Bachupally (Village), Quthubullapur Mandal, Ranga Reddy District, (A.P.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority P.O. Box 47715 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | Adopted In - house Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g Total combined Yeast/Mould Count (TYMC) NMT 20 CFU/g | TAMC < 10 CFU/g TYMC < 10 CFU/g | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 2015 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 3.7 & 5.6 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 2015 Vol. 2 Page 2226 | Amoxicillin 90-120% | Day 1 95.6% (RSD=1.9%, n=7) Day 7 90.7% (RSD=0.4%, n=9) | **COMPLIES** |
| **Assay** |  | USP 38 NF 33 2015 Vol. 2 Page 2226 | Clavulanic Acid 90.0 - 125.0% | Day 1 101.7% (RSD=1.6%, n=9) Day 7 104.9% (RSD=0.6%, n=9) |  |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 2015 Vol. 2 Page 2226 | 3.8 - 6.6 | 4.7 | **COMPLIES** |

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

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 03-16-2016 |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 04-04-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-27-2016 |