**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/335

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| **PRODUCT** | AMOXIL FORTE 250 mg/5 mL POWDER FOR 100 mL ORAL SUSPENSION | | **REF. NO: NDQD201609144** |
| **DATE RECEIVED:** 29.09.2016 | **LABEL CLAIM:** | When reconstituted as directed, each 5 ml contains amoxicillin 250 mg as amoxicillin trihydrate. | |
| **BATCH NO.:** 1073 | **PRESENTATION:** | White coloured, free flowing, granulated powder for reconstitution into oral suspension contained in a 100 mL clear glass bottle and supplied along with a beige coloured, 10 mL graduated plastic measuring spoon, packed in a unit box. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | GLAXO Wellcome Production. | |
| **EXP. DATE:**  Feb. 2018 | **ADDRESS:** | Zone Industrielle de la Peyenniere, 53100 Mayenne, FRANCE. | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique, P. O. Box 10397 - 00400, Nairobi, Kenya. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL Total Combined Yeast/Moulds Counts (TYMC) NMT 20 CFU/mL | < 10 CFU/mL < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Pg 2223 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Pg 2223 | 6.0 - 7.5 | 6.03 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Pg 2223 | 90.0 - 120.0% | Freshly Reconstituted 102.6% (RSD=1.3%; n=6) | **COMPLIES** |
| **Assay** |  |  |  | After 7 Days 100.8% (RSD=0.8%; n=6) | **COMPLIES** |

**CONCLUSION:**

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 11-11-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 12-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-14-2016 |