**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/256

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| **PRODUCT** | MYDAWA CO-AMOXICLAV 457 ORAL SUSPENSION | | **REF. NO: NDQD2016061221** |
| **DATE RECEIVED:** 23-06-2016 | **LABEL CLAIM:** | Each 5 mL reconstituted suspension contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 400 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 57 mg. | |
| **BATCH NO.:** FK175 | **PRESENTATION:** | Off white, free flowing powder for reconstitution into suspension for oral administration, contained in a 70 mL translucent plastic bottle packed along with 10 mL graduated plastic measuring cup in a printed box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | FINECURE Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | Shimla Pistaur, Malsa Road, Kichha, Udham Singh Nagar, Uttarakhand - 263148, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ION Kenya, Landmark Plaza, Arwings Khodek, Road, P. O. Box 46986-00100, 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 | BP 2016 Vol. V App XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 2226 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 3.3 & 8.0 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 page 2226 | 3.8 - 6.6 | 4.8 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 2226 | Amoxicillin 90.0 - 120.0% | Day 1 103.3% (RSD =1.4%; n=9) | **COMPLIES** |
| **Assay** |  |  | Clavulanic Acid 90.0 - 125.0% | Day 7 100.1% (RSD=1.0%; n=9) |  |
| **Assay** |  |  |  | Day 1 119.3% (RSD =1.6%; n=9) |  |
| **Assay** |  |  |  | Day 7 115.7% (RSD=1.0%; n=9) |  |

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

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| **ANALYST** | DR. LORNA WANGARI | .......................................................... | DATE: 04-10-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 11-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-16-2016 |