**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/131

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYDAWA CO - AMOXICLAV 1000 TABLETS | | **REF. NO: NDQD2016061218** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 875 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg. | |
| **BATCH NO.:** B1734 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex shaped tablets, plain on both faces, packed in an aluminium blister strip of 7 tablets and 2 such strips in a unit 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:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 page 2227 | RT of the major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.7 & 6.0-/+ 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% | Amoxicillin Trihydrate Average = 96% Range | **COMPLIES** |
| **Dissolution** |  |  | No Tablet Less than 85.0% | 91 - 101%; (RSD=5.4%, n=6) |  |
| **Dissolution** |  |  |  | Clavulanic Acid Average = 95%, Range |  |
| **Dissolution** |  |  |  | 94 - 97% (RSD=1.4%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 2227 | 90.0 - 120.0% | amoxicillin Trihydrate 105.3% (RSD=1.3%, n=9) | **COMPLIES** |
| **Assay** | HPLC |  |  | Clavulanic Acid 105.2% (RSD=0.3%, n=9) |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 06-24-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 07-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-07-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-30-2016 |