**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/138

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYDAWA LEVOFLOXACIN 750 TABLETS | | **REF. NO: NDQD2016061214** |
| **DATE RECEIVED:** 23-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Levofloxacin Hemihydrate USP equivalent to Levofloxacin 750 mg. | |
| **BATCH NO.:** FK186 | **PRESENTATION:** | Orange coloured, caplet shaped, biconvex tablets, packed in an aluminium blister strip of 10 tablets 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:** | 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 tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In - House Method | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value 8.7 ± 10% min. present in the sample preparation | **COMPLIES** |
| **Dissolution** | UV | Adopted In - House Method | No tablet less than 85% (n = 6) | Average = 94% Range |  |
| **Dissolution** |  |  |  | 88 - 102%, (RSD=5.6%, n=6) |  |
| **Assay** | HPLC | Adopted In - House Method | 95.0 - 105.0 % | 97.6% (RSD=1.6%, n=9) |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 06-24-2016 |
| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 06-24-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 07-04-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-30-2016 |