**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/79

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYDAWA CEFUROXIME 125 SUSPENSION | | **REF. NO: NDQD2016061220** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each 5 mL reconstituted suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg | |
| **BATCH NO.:** FK184 | **PRESENTATION:** | Pink coloured powder for reconstitution into suspension for oral administration, contained in a 100 mL plastic bottle packed along with a graduated plastic measuring cap 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:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 vol V Appendix XVI B & D | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | TAMC < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  |  | TYMC < 10 CFU/g |  |
| **Identification** | HPLC | USP 38 NF 33 PG 2707 | RT of the major peakS in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 15.8 & 18.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | B.P. 2012 Vol .V App XII C | 3.5 - 7.0 | 6.2 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 VOL 2 PG 2707 | 90.0 - 110.0% | Day 1 105.4% (RSD=1.1%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Day 7 104.9% ( RSD=1.9%, n=9) |  |

**CONCLUSION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 06-27-2016 |
| **DIRECTOR** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |