**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/150

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | COLDIFED-P SYRUP | | **REF. NO: NDQD201607011** |
| **DATE RECEIVED:** 05-07-2016 | **LABEL CLAIM:** | Each teaspoonful (5 mL) of syrup contains Paracetamol 120 mg, Pseudoephedrine HCl 30 mg and Triprolidine HCl 1.25 mg | |
| **BATCH NO.:** 1000023 | **PRESENTATION:** | A lime green coloured syrup contained in an amber coloured glass bottle with a child proof closure and a 15 mL graduated dispensing cup, packed in a printed box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | LIFEPharma FZE | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | Jebel Ali, Dubai, U.A.E. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd, P.O. Box 49146 - 00100 GPO, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App XVI B. | TAMC NMT 200 CFU/mL | >10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | TYMC NMT 20 CFU/mL | >10 CFU/mL |  |
| **Identification** | HPLC | Manufacturer's In-House Method | Retention time of the major peaks in the assay sample preparation correspond to those in the assay standard preparations | Super-imposable peaks at RT 3.9, 7.1 & 20.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In-House Method | 4.0 - 6.5 | 4.6 | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0 % | Paracetamol 101.6% (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Pseudoephedrine HCl 100.1% (RSD=0.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tripolidine HCl 92.6% (RSD=1.2%, n=9) | **COMPLIES** |

**CONCLUSION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 07-13-2016 |
| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 07-13-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-07-2016 |