**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/171

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | CHLORAMPHENICOL ORAL SUSPENSION | | **REF. NO: NDQD201605960** |
| **DATE RECEIVED:** 24-05-2016 | **LABEL CLAIM:** | Each 5 mL (teaspoonful) contains: Chloramphenicol Palmitate BP equivalent to Chloramphenicol 125 mg | |
| **BATCH NO.:** 150001 | **PRESENTATION:** | Yellow coloured suspension for oral administration contained in a 100 mL amber coloured glass bottle packed along with a graduated 10 mL dispensing cap in a printed box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | SHELYS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Dec. 2017 | **ADDRESS:** | Plot No. 696, New Bagamoyo Road, Mwenge, P.O. Box 32781, Dar Es Salaam, TANZANIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd, P. O. Box 42569-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Pour Plate | BP 2016 Vol. V App XVI B | Total Aerobic Microbial Count (TAMC); NMT 200 CFU/mL | TAMC <100 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts/ Moulds Count (TYMC) NMT NMT 20 CFU/mL | TYMC <10CFU/mL |  |
| **Identification** | HPLC | USP 38 NF 33 Page 2748 | Retention Time of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 15.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2748 | 90.0 - 120.0 % | 97.1% (RSD=0.6%; n=6) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2748 | 4.5 - 7.0 | 5.6 | **COMPLIES** |

**CONCLUSION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 06-27-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-12-2016 |