**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/721

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MOXICOR F SYRUP | | REF. NO: NDQD201510451 |
| **DATE RECEIVED:** 22.10.2015 | **LABEL CLAIM:** | Each 5 mL of reconstituted syrup contains: Amoxicillin Trihydtate BP Equivalent to Amoxicillin 125 mg, Flucloxacillin Sodium Bp Equivalent to Flucloxacillin 125 mg. | |
| **BATCH NO.:** BT-1501 | **PRESENTATION:** | Light pink coloured granulated powder for reconstitution into suspension for oral administration contained in a 100 mL translucent plastic bottle, packed along with a 10 mL graduated measuring cap in a unit box. | |
| **MGF. DATE:** Jun. 2015 | **MANUFACTURER:** | CORAL Laboratories Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Plot No.27/28, Pharmacity, Selaqui, Dehradun, Uttarakhand - 248 197, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | TWOKAY CHEMICALS LTD P.O BOX 46169-00100 NAIROBI,KENYA | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.6 and 12.9 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** |  | Adopted In-House Method | Day 1: 90.0% - 120.0% Day 7: 80.0% - 120.0% | Day 1 Amoxicillin Trihydrate 99.5% (RSD=0.5%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | Day 1: 90.0% - 120.0% Day 7: 80.0% - 120.0% | Flucloxacillin 119.8% (RSD=1.5%, n=9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | Day 1: 90.0% - 120.0% Day 7: 80.0% - 120.0% | Day 7 Amoxicillin Trihydrate 110.6% (RSD=1.2%, n=9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | Day 1: 90.0% - 120.0% Day 7: 80.0% - 120.0% | Flucloxacillin 119.6% (RSD=0.8%, n=9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** |  | BP 2016 Vol. V App XII C | 4.0 - 7.5 | 5.2 | **COMPLIES** |
| **Microbial Load** |  | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g | **COMPLIES:COMPLIES** |
| **Microbial Load** |  | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU /g | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. F. NAULA |  | DATE:10-27-2015 |
| ANALYST: | DR. E. MUTUA |  | DATE:12-21-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:05-24-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-14-2016 |