**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/464

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ELYMOX POWDER for RECONSTITUTION | | REF. NO: NDQA201509337 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each 5 mL of suspension when freshly prepared contains; Amoxicillin Trihydrate B.P. equivalent to Amoxicillin 125 mg. | |
| **BATCH NO.:** 4A56 | **PRESENTATION:** | Off-white powder for reconsititution into suspension for oral administration, contained in a 100 mL translucent plastic bottle in a unit box. | |
| **MGF. DATE:** Jan.2014 | **MANUFACTURER:** | ELYS Chemical Industries Ltd. | |
| **EXP. DATE:**  Dec.2016 | **ADDRESS:** | Road B, Off Enterprise Road, P.O. Box 40411 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMO/10/09/03/2015/00011 | **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 | Total Aerobic Microbial Count(TAMC) NMT 200 CFU/g Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g < 10 CFU/g | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2223 | RT of the major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT; 4.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2223 | 90.0 - 120.0% | Day 1 98.9% (RSD=1.9%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2223 | 90.0 - 120.0% | Day 7 90.1% (RSD=0.1%; n=6) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2223 | 5.0 - 7.5 | 5.2 | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. F. NAULA |  | DATE:15-03-2016 |
| ANALYST: | DR. E. MUTUA |  | DATE:15-03-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:15-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-22-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-04-2016 |