**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/233

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| **PRODUCT** | ELYMOX POWDER ORAL SUSPENSION 125 mg/5 mL | | **REF. NO: NDQD201609094** |
| **DATE RECEIVED:** 08.09.2016 | **LABEL CLAIM:** | Composition: Each 5 mL of suspension when freshly prepared contains: Amoxicillin Trihydrate B.P. equivalent to Amoxicillin 125 mg. | |
| **BATCH NO.:** 6E36 | **PRESENTATION:** | Off-white powder for reconstitution into suspension for oral administration, contained in a 100 mL translucent plastic bottle in a unit box. | |
| **MFG. DATE:** May 2016 | **MANUFACTURER:** | ELYS Chemical Industries Ltd. | |
| **EXP. DATE:**  Apr. 2019 | **ADDRESS:** | Unit 2, Mombasa Road, P.O. Box 40411 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | ELYS CHEMICAL INDUSTRIES LTD. P. O. BOX 40411 - 00100 NAIROBI, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Assay, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Assay** | 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 | TAMC; <10 CFU/g, TYMC; <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 4.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2223 | 5.0 - 7.5 | 5.8 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2223 | 90.0 - 120.0% | Day 1 104.3% (RSD=0.6%; n=8) | **COMPLIES** |
| **Assay** |  |  |  | Day 7 107.4% (RSD=0.5%; n=6) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 10-11-2016 |
| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 10-11-2016 |
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| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-10-2016 |