**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/214

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| **PRODUCT** | SULFRAN PAEDIATRIC SUSPENSION | | **REF. NO: NDQB201610153** |
| **DATE RECEIVED:** 06-10-2016 | **LABEL CLAIM:** | Each 5 mL contains Trimethoprim BP 40 mg and Sulphamethoxazole BP 200 mg. | |
| **BATCH NO.:** 610183 | **PRESENTATION:** | Pink coloured flavoured suspension for oral administration contained in an amber coloured 100 mL plastic bottle packed along with a clear 10 mL graduated plastic cap in a printed box. | |
| **MFG. DATE:** Aug. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Jul. 2019 | **ADDRESS:** | Club Road, Plot No. 13777, P. O. Box 1748 - 00902, Kikuyu, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 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** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL | <10CFU/mL | **COMPLIES** |
| **Microbial Assay** |  |  | Total Combined Yeast/Moulds Count (TYMC) NMT 20 CFU/mL | <10CFU/mL |  |
| **Identification** | HPLC | USP 38 NF 33 page 5397 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 4.4 & 6.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 page 5397 | 5.0 - 6.5 | 5.7 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 5397 | 90.0 - 110.0% | Sulphamethoxazole 93.5% (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Trimethoprim 91.4% (RSD=0.8%, n=9) |  |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-10-2016 |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 10-10-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 21-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-26-2016 |