**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/38

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| **PRODUCT** | SULFRAN PAEDIATRIC SUSPENSION | | **REF. NO: NDQB2016061169** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each 5 mL contains Trimethoprim B.P 40 mg and Sulphamethoxazole B.P 200 mg. | |
| **BATCH NO.:** 610006 | **PRESENTATION:** | Pink coloured suspension for oral administration in a 100 mL amber coloured plastic bottle and supplied along with a 10 mL graduated clear plastic measuring cap, packed in a unit box. | |
| **MFG. DATE:** Jan. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Dec. 2018 | **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. | |
| COT/24/05/2016/137 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol V App XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | TAMC < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeast/Moulds Count (TYMC) NMT 20 CFU/mL | TYMC < 10 CFU/mL |  |
| **Identification** | HPLC | USP 38 NF 33 Page 5397 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.2 & 7.4 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397 | 90.0 -110.0% | Trimethoprim 97.3% (RSD=1.9%; n=6) | **COMPLIES** |
| **Assay** |  |  |  | Sulphamethoxazole 96.1% (RSD=1.1%; n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 5397 | 5.0 - 6.5 | 5.9 | **COMPLIES** |

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

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| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |