**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | SULFRAN PAEDITRIC SUSPENSION | | REF. NO: NDQA201509370 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each 5 mL contains: Trimethoprim BP 40 mg and Sulphamethoxazole B.P 200 mg. | |
| **BATCH NO.:** 410220 | **PRESENTATION:** | Pink coloured, viscous suspension for oral administration, contained in a 100 mL amber coloured plastic bottle, packed along with a 10 mL graduated plastic measuring cap in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:** Aug. 2017 | **ADDRESS:** | Club Road, Plot No. 13777, P.O. Box 1748-00902, Kikuyu, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.o Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count Method | BP 2013 Vol. V App. XVIB | Total Aerobic Microbial Count (TAMC) 200 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) 20 CFU/mL | < 200 TAMC CFU Per mL < 20 TYMC CFU Per mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Vol.3 Page 5398 | RT of the component Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 3.2 and 6.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol.3 Page 5398 | 90.0% - 110.0% | sulphamethoxazole; 97.2% (RSD = 1.5%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol.3 Page 5398 | 90.0% - 110.0% | Trimethoprim; 93.8% (RSD = 1.8%, n=9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Vol.3 Page 5398 | 5.0 - 6.5 | 5.6 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:28-12-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:28-12-2015 |
| ANALYST: | DR. M. KWENA |  | DATE:28-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-29-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-14-2016 |