**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | SULFRAN PAEDIATRIC SUSPENSION | | REF. NO: NDQD201508060 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each 5 mL contains: Trimethoprim B.P. 40 mg and Sulphamethoxazole B.P 200 mg. | |
| **BATCH NO.:** 510025 | **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:** Jan.2015 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:** Dec.2017 | **ADDRESS:** | Club Road, Plot No. 13777, P.O. Box 1748 ÃƒÂ¢Ã¢â€šÂ¬Ã¢â‚¬Å“ 00902, Kikuyu, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique P.O. Box 10397 - 00400, Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | pH, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **pH** |  | USP 38 NF 33 Vol 3 Page 5397 | 4.5 - 6.5 | 5.8 | **COMPLIES** |
| **Microbial Load** | Plate count | In House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL ::: | < 200 TAMC CFU Per ML | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate count | In House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL ::: | < 20 TYMC CFU Per mL | **COMPLIES:COMPLIES** |
| **Identification** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation |  | **COMPLIES** |
| **Identification** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 5.6 and 10.5 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Identification** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation |  | **COMPLIES** |
| **Identification** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation |  | **COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | 90.0% - 110.0% | Trimethoprim 92.6% (RSD=0.5%,n=6) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol 3 Page 5397 | 90.0% - 110.0% | Sulphamethoxazole 99.4% (RSD=0.9%,n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:11-09-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:11-09-2015 |
| ANALYST: | DR. E MBAE |  | DATE:06-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-12-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-14-2015 |