**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/795

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| **PRODUCT** | SULFRAN-DS TABLETS | | REF. NO: NDQB201605926 |
| **DATE RECEIVED:** 12.05.2016 | **LABEL CLAIM:** | Each tablet contains: Sulphamethoxazole BP 800 mg and Trimethoprim BP 160 mg. | |
| **BATCH NO.:** 620477 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a blister strip of 10 tablets and 10 such strips packed in a unit box. | |
| **MGF. DATE:** Mar. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Feb. 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:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | USP 38 NF 33 Page 5399 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 2.7 and 4.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | Sulphamethoxazole 87.2% (RSD=0.1%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | Trimethoprim 86.2% (RSD=0.12%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Sulphamethoxazole 97.8% (RSD=1.2%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Trimethoprim 97.4% (RSD=0.4%, n=9) | **COMPLIES:COMPLIES** |
| **Uniformity of Weight** |  | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:17-06-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:25-06-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:06-28-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-30-2016 |