**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | SULFRAN DS TABLETS | | REF. NO: NDQB201512622 |
| **DATE RECEIVED:** 08.12.2015 | **LABEL CLAIM:** | Each tablet contains Sulphamethoxazole B.P. 800 mg and Trimethoprim B.P. 160 mg. | |
| **BATCH NO.:** 521493 | **PRESENTATION:** | White coloured, caplet shaped tablets, single scored on one face and plain on the other, packed in blister strips in a unit box containing 10 strips of 10 tablets each. | |
| **MGF. DATE:** Nov. 2015 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:** Oct. 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 | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol V App XIIC | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5399 | RT of component peaks in the sample assay preparation correspond to those in the standard assay preparation | Super-imposable peaks at RT 4.1 and 7.8 min -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | Sulphamethoxazole | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | 94.5% (RSD = 1.3%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | Trimethoprim | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | No tablet less than 75% [n=6] | 93.6% (RSD = 0.9%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Sulphamethoxazole | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | 99.8% (RSD = 0.6%, n=9) Trimethoprim | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | 97.9% (RSD = 0.4%, n=9) | **COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:12-16-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:12-28-2015 |
| REVIEWER: | SERAH MUTERU |  | DATE:07-01-2016 |
| ANALYST: | SERAH MUTERU |  | DATE:01-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-12-2016 |