**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/478

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| **PRODUCT** | SULFRAN - DS TABLETS | | REF. NO: NDQD201602751 |
| **DATE RECEIVED:** 18.02.2016 | **LABEL CLAIM:** | Each tablet contains: Sulphamethoxazole B.P. 800 mg and Trimethoprim B.P. 160 mg. | |
| **BATCH NO.:** 521619 | **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:** Dec. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Limited. | |
| **EXP. DATE:**  Nov. 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 XII C | NMT 2 tablets deviate by more than 5% from the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted 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 peaks at RT 4.0 and 7.9-/+ 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 100.8% (RSD=0.8%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | No Tablet Less Than 75% [n=6] | Trimethoprim 103.2% (RSD=1.2%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Sulphamethoxazole 96.0% (RSD=1.0%, n=) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Trimethoprim 96.4% (RSD=1.1%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:23-03-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:01-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-06-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-06-2016 |