**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/206

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| **PRODUCT** | SULFRAN - DS TABLETS | | **REF. NO: NDQB201610149** |
| **DATE RECEIVED:** 04-10-2016 | **LABEL CLAIM:** | Each tablet contains: Sulphamethoxazole BP 800 mg and Trimethoprim BP 160 mg. | |
| **BATCH NO.:** 621711 | **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 in a printed box. | |
| **MFG. DATE:** Sep. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Aug. 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** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 5399 | RT of the major peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 4.4 & 6.5 -/+ 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 Average = 98% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 97 - 99% (RSD = 0.8%; n = 6) |  |
| **Dissolution** |  |  |  | Trimethoprim Average = 100% Range |  |
| **Dissolution** |  |  |  | 99 -101% (RSD = 0.6%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 5399 | 93.0 - 107.0% | Sulphamethoxazole 100.3% (RSD = 0.7%; n = 9) | **COMPLIES** |
| **Assay** |  |  |  | Trimethoprim 101.7% (RSD = 1.3%; n = 9) |  |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-10-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 21-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-25-2016 |