**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/24

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| **PRODUCT** | SULFRAN - DS TABLETS | | **REF. NO: NDQD201507018** |
| **DATE RECEIVED:** 2016-07-14 | **LABEL CLAIM:** | Each tablet contains: Sulphamethoxazole B.P. 800 mg and Trimethoprim B.P. 160 mg. | |
| **BATCH NO.:** 621104 | **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:** Jun. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  May 2019 | **ADDRESS:** | Club Road, Plot No. 13777, P.O Box 1748-00902, Kikuyu, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | COOPER K - BRAND LTD P.O BOX 40596 - 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 2012 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from the mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 2015 Vol. 3 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 4.7 & 8.6 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Identification** |  |  |  |  |  |
| **Dissolution** | HPLC | USP 38 NF 33 2015 Vol. 3 Page 5399 | No Tablet Less Than 75% [n=6] | Trimethoprim Average = 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 88% - 91% (RSD=1.3%; n=6) |  |
| **Dissolution** |  |  |  | Sulphamethoxazole Average = 92% Range |  |
| **Dissolution** |  |  |  | 91% - 93% (RSD=1.0%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 2015 Vol. 3 Page 5399 | 93.0 - 107.0% | Trimethoprim 101.2% (RSD=1.7%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Sulphamethoxazole 102.2% (RSD=1.4%; n=9) |  |

**CONCLUSION:** The sample complies with the specifications of the tests perfomed.

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| **ANALYST** | DR. LORNA WANGARI | .......................................................... | DATE: 19-07-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 20-07-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-27-2016 |