**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/216

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| **PRODUCT** | UNITRIM 480 mg TABLETS | | **REF. NO: NDQD201609099** |
| **DATE RECEIVED:** 08-09-2016 | **LABEL CLAIM:** | Each tablet contains: Trimethoprim BP 80 mg and Sulfamethoxazole BP 400 mg. | |
| **BATCH NO.:** 160979 | **PRESENTATION:** | Off white coloured, circular shaped, flat faced, bevel edged tablets, single scored on one face and embossed 'CO-TRIM' and 480 on alternate sides of the score and 'REGAL' on the other, 1000 tablets packed in a black plastic multidose container. | |
| **MFG. DATE:** Jun. 2016 | **MANUFACTURER:** | REGAL Pharmaceuticals Ltd. | |
| **EXP. DATE:**  May 2020 | **ADDRESS:** | Plot No.7879/18, Off Baba Dogo Road, Ruaraka, P. O. Box 44421 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | REGAL Pharmaceuticals Ltd., P. O. BOX 44421 - 100 Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, Dissolution, Disintegration, 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 correspond to those in the assay standard preparation | Super-imposable peaks at RT 4.4 & 6.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Friability** | Weight | BP 2016 Vol. V App. XVII G | Percentage weight loss is NMT 1.0% | 0.6% | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App. XII A | All tablets disintegrates within 30 minutes | All tablets disintegrated within 1 minute. | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 page 5399 | No tablet less than 75% [n=6] | Sulfamethoxazole Average 96% Range 94 - 99% (RSD = 2.3%; n = 6) |  |
| **Dissolution** |  |  |  | Trimethoprim Average 99% Range 97 - 102% (RSD = 2.1%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 5399 | 93.0 - 107.0% | Sulfamethoxazole 97.6% (RSD = 0.5%; n = 6) | **COMPLIES** |
| **Assay** |  |  |  | Trimethoprim 95.1% (RSD = 0.7%; n = 6) |  |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 21-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-02-2016 |