**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | SULFAMETHOXAZOLE and TRIMETHOPRIM TABLETS USP 960 mg | | REF. NO: NDQA201509390 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains 800 mg Sulfamethoxazole USP and 160 mg Trimethoprim USP | |
| **BATCH NO.:** XN140751 | **PRESENTATION:** | White coloured, oval shaped, biconvex faced tablets, packed in blister strips of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Jul. 2014 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co., Ltd. | |
| **EXP. DATE:** Jul. 2017 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/06/10.3.2015/00061 | **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. IV App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | 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 4.1 and 7.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% | SULPHAMETHOXAZOLE 93.9% (RSD = 2.6%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% | TRIMETHOPRIM 86.9% (RSD = 2.5%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | SULPHAMETHOXAZOLE 100.3% (RSD = 1.6%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | TRIMETHOPRIM 98.8% (RSD = 1.7%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:15-01-2016 |
| REVIEWER: |  |  | DATE:15-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-20-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-25-2016 |