**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ASTRIM TABLETS | | REF. NO: NDQD201509392 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each uncoated tablet contains: Trimethoprim BP 80 mg, Sulfamethoxazole BP 400 mg and excipients q.s. | |
| **BATCH NO.:** 581 | **PRESENTATION:** | White coloured, flat-faced, circular shaped, bevel-edged tablets, single scored and alternately embossed "COTRI" and "480" on either side of the score on one face, but plain on the opposite face packed in a high density plastic container carrying 1000 tablets. | |
| **MGF. DATE:** Mar.2014 | **MANUFACTURER:** | ASTRA Lifecare(India) Pvt Ltd. | |
| **EXP. DATE:** Mar.2017 | **ADDRESS:** | Plot No. 57/P, Sarkhej-Bavla Highway, Post. Rajoda-382220, Takula: Bavla, Dist. Ahmedabad, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/01/9.3.15/00003 | **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. 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 peak at RT 4.1 and 7.9 -/+ 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% [n=6] | SULFAMETHOXAZOLE 95.6% (RSD = 2.1%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% [n=6] | TRIMETHOPRIM 98.0% (RSD = 1.4%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | SULFAMETHOXAZOLE 97.5% (RSD = 0.8%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | TRIMETHOPRIM 97.3% (RSD=0.5%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:18-01-2016 |
| REVIEWER: | DR. E. TANUI |  | DATE:18-01-206 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-20-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-25-2016 |