**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ASTRIM TABLETS | | REF. NO: NDQA201509391 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains: Sulfamethoxazole B.P. 400 mg, Trimethoprim B.P. 80 mg | |
| **BATCH NO.:** 581 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel-edged tablets, single scored and alternately embossed "COTRI" and "480" on either side of the score on one face, and plain on the opposite side, packed loosely in a brown paper dispensing envelope. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | ASTRA Lifecare (India) Pvt Ltd. | |
| **EXP. DATE:** Feb. 2017 | **ADDRESS:** | Plot No.57/P Sarkhej-Bavla Highway, Post Rajoda-382220, Dist. Ahmedabad. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/02/10/03/2015/00044 | **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% | SULPHAMETHOXAZOLE 95.9% (RSD = 0.7%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% | TRIMETHOPRIM 96.3% (RSD = 0.8%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | SULPHAMETHOXAZOLE 98.5% (RSD=0.5%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | TRIMETHOPRIM 98.1% (RSD = 1.0%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:15-01-2015 |
| REVIEWER: | DR. E. TANUI |  | DATE:15-01-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-20-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-25-2016 |