**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | Cosatrim DS Tablets | | REF. NO: NDQA201509396 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains Sulfamethoxazole BP 800mg & Trimethoprim BP 160mg | |
| **BATCH NO.:** 11274 | **PRESENTATION:** | White coloured oval shaped, biconvex faced tablets, single scored on one face, embossed "COSATRIM" "DS" on the opposite unscored face, packed in blister pack of 10 and such 10 blisters in a unit box. | |
| **MGF. DATE:** Jul.2011 | **MANUFACTURER:** | COSMOS Limited | |
| **EXP. DATE:** Jun.2016 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road P.O. Box 41433 - 00100, Nairobi, KENYA | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/07/11.032015/00210 | **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 .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 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 peak at RT 4.1,7.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 2015 VOL 3 Page 5399 | After 60 Mins:No tablet is less than 75% | SULPHAMETHOXAZOLE 96.6% (RSD = 2.24%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 2015 VOL 3 Page 5399 | After 60 Mins:No tablet is less than 75% | TRIMETHOPRIM 98.1% (RSD = 0.88%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 2015 VOL 3 Page 5399 | 93-107 | SULPHAMETHOXAZOLE 97.4 (RSD = 0.05%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 2015 VOL 3 Page 5399 | 93-107 | TRIMETHOPRIM 97.62% (RSD = 1.27%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:13-01-2016 |
| REVIEWER: | DR. E. TANUI |  | DATE:13-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-20-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-25-2016 |