**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | CO-TRI TABLETS | | REF. NO: NDQA201509387 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains Sulfamethoxazole 400 mg and Trimethoprim 80 mg | |
| **BATCH NO.:** 3D39 | **PRESENTATION:** | White coloured, circular shaped, flat-faced, bevel-edged tablets, single scored and embossed "CO-TRI" on one side of the score on one face and "GOK" on the opposite, unscored face, loosely packed in a transparent polythene packet. | |
| **MGF. DATE:** Apr. 2013 | **MANUFACTURER:** | ELYS Chemical Industries Ltd. | |
| **EXP. DATE:** Mar. 2017 | **ADDRESS:** | Road B, Off Enterprise Road, P.O Box 40411 - 00100 Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/03/13/03/2015/00210 | **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. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC: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 4.2 and 7.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% [n=6] | Sulfamethoxazole 95.7% (RSD = 4.8%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% [n=6] | Trimethoprim 100.5% (RSD = 4.4%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Sulfamethoxazole 99.3% (RSD = 0.85%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Trimethoprim 98.9% (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:22-01-2016 |
| REVIEWER: | EMMANUEL TANUI |  | DATE:22-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-26-2016 |