**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/295

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| **PRODUCT** | ETHAM-400 TABLETS | | **REF. NO: NDQB201609120** |
| **DATE RECEIVED:** 2016-09-27 | **LABEL CLAIM:** | Each film coated tablet contains: Ethambutol HCl BP 400 mg. | |
| **BATCH NO.:** 60941 | **PRESENTATION:** | Orange coloured, circular shaped, biconvex faced tablets, embossed â€˜Câ€™ on one face and plain on the other, packed in blister strips in a unit box containing 28 tablets. | |
| **MFG. DATE:** Aug. 2016 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Jul. 2020 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Rd., P. O. Box 41433 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **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 | Adopted USP 39 NF 34 Pg 3810 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted USP 39 NF 34 Pg 3810 | No tablet less than 80.0% | 94.0% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93.6 - 94.6%) (RSD=0.4%; n=6) |  |
| **Assay** | HPLC | USP 39 NF 34 Pg 3810 | 95.0 - 105.0% | 96.5% (RSD=0.8%; n=9) | **COMPLIES** |

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

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| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 24-10-2016 |
| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 24-10-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |