**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/406

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| **PRODUCT** | ISONIAZID TABLETS BP 100 mg | | REF. NO: NDQB201601714 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains: Isoniazid B.P 100 mg | |
| **BATCH NO.:** 50574 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'COSMOS' on the opposite, unscored face, packed in blister strips of 10 tablets each and 10 such strips in a unit box. | |
| **MGF. DATE:** Feb 2015 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Jan 2019 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road, 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** | **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 tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3955 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 3955 | No Tablet Less than 85% [n=6] | 106.4% (RSD=0.7%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3955 | 90.0 - 110.0% | 98.4% (RSD=0.2%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:15-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:25-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-01-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-02-2016 |