**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/407

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| **PRODUCT** | ISONIAZID TABLETS BP 300 mg | | REF. NO: NDQB201601715 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each uncoated tablet contains: Isoniazid B.P. 300 mg. | |
| **BATCH NO.:** EIW486A | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablets, packed in a blister strip of 28 tablets and 24 such strips in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Aug. 2018 | **ADDRESS:** | Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, INDIA. | |
| **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 | B.P. 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 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] | 97.5% (RSD=1.7%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3955 | 90.0 - 110.0% | 99.1% (RSD=1.4%; 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:25-10-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-01-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-02-2016 |