**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/765

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| **PRODUCT** | RIFAMPICIN 150 mg and ISONIAZID 75 mg | | REF. NO: NDQD2016061094 |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film coated tablet contains Rifampicin BP 150 mg and Isoniazid BP 75 mg. | |
| **BATCH NO.:** ERC4516B | **PRESENTATION:** | Brick red coloured, round shaped, biconvex faced tablets, plain on one both faces, packed in a blister strip of 28 tablets. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P. O. Box 19361, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | USP 38 NF 33 Page 5176 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 2.8 and 8.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Isoniazid 87.% (RSD=4.3%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Rifampicin 86.4% (RSD=5.0%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Isoniazid 97.3% (RSD=0.8%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Rifampicin 94.0% (RSD=0.9%, n=6) | **COMPLIES:COMPLIES** |
| **Uniformity of Weight** |  | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:14-06-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:18-06-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:06-24-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-30-2016 |