**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/839

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| **PRODUCT** | RIFAMPICIN 150 mg - ISONIAZID 75 mg TABLETS | | **REF. NO: NDQD201511515** |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Rifampicin USP 150 mg and Isoniazid USP 75 mg. | |
| **BATCH NO.:** A303166 | **PRESENTATION:** | Brick red coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a blister strip of 28 tablets and 12 such strips in a unit box. | |
| **MGF. DATE:** Jun. 2013 | **MANUFACTURER:** | LUPIN Ltd. | |
| **EXP. DATE:**  May 2016 | **ADDRESS:** | A-28/1, M.I.D.C. Chikalthana, Aurangabad - 431 210, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | NATIONAL TUBERCULOSIS, LEPROSY & LUNG DISEASE PROGRAM P.O Box 20781 - 00202, KNH, Nairobi, KENYA | |
| RH/05/17.03.2015/00339 | **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 | Adopted USP 38 NF 33 Page 5176 | RT of the component peaks in the sample preparation correspond to those in the standard preparation | Super-imposable peaks at RT 3.6 and 9.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted USP 38 NF 33 Page 5176 | No Tablet Less Than 80% [n=6] | Isoniazid 95.6% (RSD=2.9%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Rifampicin 97.1% (RSD=2.2%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted USP 38 NF 33 Page 5176 | 90.0 - 110.0% | Isoniazid 90.1% (RSD=1.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Rifampicin 93.8% (RSD=1.4%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 27-05-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 09-06-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |