**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/810

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| **PRODUCT** | RIFAMPICIN 150 mg - ISONIAZID 75 mg - PYRAZINAMIDE 400 mg - ETHAMBUTOL HYDROCHLORIDE 275 mg TABLETS | | **REF. NO: NDQD201511524** |
| **DATE RECEIVED:** 03.11.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Rifampicin USP 150 mg, Isoniazid USP 75 mg, Pyrazinamide USP 400 mg and Ethambutol Hydrochloride USP 275 mg. | |
| **BATCH NO.:** A303319 | **PRESENTATION:** | Brick red coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a red blister strip of 28 tablets. | |
| **MGF. DATE:** Jul. 2013 | **MANUFACTURER:** | LUPIN Ltd. | |
| **EXP. DATE:**  Jun. 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 | |
| RHZE/9/10.03.2015/00143 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | 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 peaks at RT 2.5, 2.9, 4.5 and 7.5, -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Ethambutol hydrochloride 90.3% (RSD=0.5%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Isoniazid 90.5% (RSD=0.3%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Pyrazinamide 92.9% (RSD=0.3%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Rifampicin 85.5% (RSD=0.3%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5176 | 90.0 - 110.0% | Ethambutol hydrochloride 100.5% (RSD=1.1%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Isoniazid 102.6% (RSD=1.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Pyrazinamide 104.84%, (RSD=1.6%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Rifampicin 96.4% (RSD=1.0%, n=9) | **COMPLIES** |
| **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** |

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

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| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 14-06-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 20-06-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 06-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 06-30-2016 |