**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** 0

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| **PRODUCT** | RIFAMPICIN 150 mg and ISONIAZID 75 mg | | REF. NO: NDQD2016061095 |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Rifampicin USP 150 mg and Isoniazid USP 75 mg. | |
| **BATCH NO.:** A404879 | **PRESENTATION:** | Brown coloured, caplet shaped, biconvex faced tablets, plain on one face and single scored on the other, packed in a blister strip of 28 tablets in a zip lock polythene pocket. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | LUPIN Ltd. | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | A-28/1, M.I.D.C. Chikalthana, Aurangabad - 431 210. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P. O. Box 19361, Nairobi, KENYA | |
| RH/10/9.03.2016/0091 | **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 2.7 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 88.7% (RSD=3.7%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Rifampicin 88.9% (RSD=3.4%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Isoniazid 96.8% (RSD=1.7%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Rifampicin 97.9% (RSD=0.7%, n=9) | **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. N. MWAURA |  | DATE:21-06-2016 |