**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** 0

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| **PRODUCT** | RIFAMPICIN 150 mg, ISONIAZID 75 mg, PYRAZINAMIDE 400 mg and ETHAMBITOL Hcl 275 mg TABLETS USP | | REF. NO: NDQD201511518 |
| **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.:** SL2426 | **PRESENTATION:** | Brown coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a blister strip of 28 tablets in a zip lock polythene pocket. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | SVIZERA Labs Pvt. Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Plot No. D-1616, TTC Ind. Area, MIDC, Turbhe, Navi, Mumbai-400 703 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | NATIONAL TUBERCLOSIS, LEPROSY & LUNG DISEASE - PROGRAM P.O BOX- | |
| RHZE/05/17.03.2015/00347 | **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 peaks at RT 2.7, 3.1, 4.5 and 6.4, -/+ 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] | Ethambutol hydrochloride 91.9% (RSD=0.23, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Isoniazid 90.4% (RSD=0.23%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Pyrazinamide 96.9% (RSD=0.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Rifampicin 96.1% (RSD=0.6%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Ethambutol hydrochloride 104.4% (RSD=1.8%, n=7) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Isoniazid 92.9% (RSD=1.3%, n=9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Pyrazinamide 99.6% (RSD=1.8%, n=7 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Rifampicin 102.8% (RSD=1.7%, n=9) | **COMPLIES:COMPLIES: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: | MR. M. SANGALE |  | DATE:13-06-2016 |
| ANALYST: | DR. G. WANGANGA |  | DATE:17-06-2016 |