**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/835

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | RH COM TABLETS | | **REF. NO: NDQD201511517** |
| **DATE RECEIVED:** 03.11.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Rifampicin BP 150 mg and Isoniazid BP 75 mg. | |
| **BATCH NO.:** KRD8310A | **PRESENTATION:** | Maroon coloured, circular shaped, biconvex faced tablets, plain on one face and embossed 'GOK' on the other, packed in a blister strip of 28 tablets. | |
| **MGF. DATE:** May 2013 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd | |
| **EXP. DATE:**  Apr. 2016 | **ADDRESS:** | Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | NATIONAL TUBERCULOSIS, LEPROSY & LUNG DISEASE PROGRAM P.O. Box 20781 - 00202, KNH, Nairobi, KENYA | |
| RH/09/11.03.2015/00205 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 assay 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 87.1% (RSD=6.1%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Rifampicin 87.5% (RSD=3.8%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted USP 38 NF 33 Page 5176 | 90.0 - 110.0% | Isoniazid 93.8% (RSD=1.7%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Rifampicin 95.1% (RSD=1.3%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |