**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ROSUMAC - 10 TABLETS | | REF. NO: NDQD201511567 |
| **DATE RECEIVED:** 19.11.2015 | **LABEL CLAIM:** | Each film coated tablet contains; Rosuvastatin Calcium equivalent to Rosuvastatin 10 mg. | |
| **BATCH NO.:** TDR(1914)232 | **PRESENTATION:** | Pink coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in an aluminium foil strip of 10 tablets and 3 such strips in a unit box. | |
| **MGF. DATE:** Feb. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jan. 2017 | **ADDRESS:** | Plot No. 25-27, Survey No. 366, Premier Ind. Estate, Kachigam, Daman - 396 210 (U.T.) Off.: Atlanta Arcade, Marol Church Road,, Andheri (E), Mumbai - 400 059, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Macleods Pharmaceuticals Ltd ? Sai Pharmaceuticals Limited PO Box 66551-00800 Nairobi, KENYA | |
|  | **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 7.5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No Less than 70% [n=6] | 101.7% (RSD=2.2%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0-105.0% | 102.5% (RSD=0.5%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. D. MOENGA |  | DATE:15-02-2016 |
| REVIEWER: | DR. S. MUTERU |  | DATE:15-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-16-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-22-2016 |