**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/105

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYDAWA ROSUVASTATIN 20 mg TABLETS | | **REF. NO: NDQD2016061211** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablet contains: Rosuvastatin calcium equivalent to Rosuvastatin 20 mg | |
| **BATCH NO.:** R5415 | **PRESENTATION:** | Green coloured, circular shaped, biconvex faced tablets, plain on both faces, ten tablets packed in an aluminium blister strip and 3 such blister strips in a unit box. | |
| **MFG. DATE:** Oct. 2015 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Sep.2017 | **ADDRESS:** | 137-B, Old Mahabalipuram Road, Karapakkam, Chennai - 600 096. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ION Kenya, Landmark Plaza, Arwings Khodek, Road, P. O. Box 46986-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | Manufacturer's In-house Method | Acceptable value of 10 units is not more than 15% [n=10] | Av = 12% (n=6) | **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 8.2-/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-house Method | No tablet is less than 75% | Average 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89 - 90% (RSD=0.9%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In-house Method | 90.0 - 110.0% | 104.4% (RSD=0.7%, n=9) | **COMPLIES** |

**CONCLUSION:** The product complies with specifications for the test performed

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 02/09/2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 02/09/2016 |
| **DIRECTOR** | DR. H. K. CHEMPKWONY | .......................................................... | DATE: 02/09/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |