**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/111

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| **PRODUCT** | MYDAWA ATORVASTATIN 20 mg TABLETS | | **REF. NO: NDQD2016061206** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablets contains Atorvastatin calcium equivalent to Atorvastatin 20 mg. | |
| **BATCH NO.:** R1516 | **PRESENTATION:** | Orange coloured, circular shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in an aluminium blister pack of 10 tablets and 3 blister packs in a unit box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Mar. 2018 | **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**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | Manufacturer's In-house Method | Acceptable value of 10 dosage units is NMT 15% | AV = 8% (n=10) | **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 2.7 -/+ 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 = 95% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 91 - 99% (RSD=3.4%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In-house Method | 90.0 - 110.0% | 99.7% (RSD=1.0%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 08-29-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 23-09-2016 |
| **ANALYST:** |  | .......................................................... | DATE: 09-23-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |