**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/74

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| **PRODUCT** | MYDAWA MONTELUKAST 10 mg TABLETS | | **REF. NO: NDQD2016061208** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablet contains Montelukast sodium equivalent Montelukast 10 mg | |
| **BATCH NO.:** M150069 | **PRESENTATION:** | Yellow, circular shaped, biconvex faced tablets, plain on both sides, packed in blister strips of 10 tablets in a unit box. | |
| **MFG. DATE:** Jan 2015 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Dec 2016 | **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 (AV) of 10 units is NMT 15% | AV= 6% (n=10) | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-house method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-house method | No tablet is less than 70% [n=6] | Average = 101% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 106% (RSD=5.1%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In-house method | 90%-110% | 94.4% (RSD=0.9%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 30/08/2016 |
| **REVIEWER** | DR.E. MBAE | .......................................................... | DATE: 30/08/2016 |
| **DIRECTOR** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |