**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/75

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| **PRODUCT** | MYDAWA CLOPIDROGEL 75 mg TABLETS | | **REF. NO: NDQD2016061207** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablet contains Clopidrogel Bisulfate USP equivalent to Clopidrogel 75 mg | |
| **BATCH NO.:** R1916 | **PRESENTATION:** | Red coloured, circular shaped, biconvex faced tablets, plain on both sides, packed in an aluminum blister strip of 10 tablets and 3 such strips in a unit box. | |
| **MFG. DATE:** Apr 2016 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Mar 2018 | **ADDRESS:** | 137-B, Old Mahabalipuram Road, Karapakkan, 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=4% (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 4.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 85% (n=6) | Average =103%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 101 - 105% (RSD=1.2%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Clopidogrel 102.4% (RSD=1.1%, n=9, ) | **COMPLIES** |
| **Assay** |  |  |  |  |  |

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

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| **ANALYST:** | DR. M. KEWNA | .......................................................... | DATE: 26-/08/2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 26/08/2016 |
| **REVIEWER** | DR.E. MBAE | .......................................................... | DATE: 26/08/2016 |
| **DIRECTOR** | DR.H. K. CHEPKWONY | .......................................................... | DATE: 26/08/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |