**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/73

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| **PRODUCT** | MYDAWA AZITHROMYCIN 500 mg TABLETS | | **REF. NO: NDQD2016061212** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each film coated tablet contains Azithromycin dihydrate USP equivalent to Anhdrous Azithromycin 500 mg | |
| **BATCH NO.:** M150245 | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets single scored on one face and plain on the other, packed in in blister strip of 3 tablets in a unit box. | |
| **MFG. DATE:** Mar. 2015 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Feb. 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 Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2348 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2348 | No tablet less than 85% | Average = 90%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 85 - 94% (RSD=3.2%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2348 | 90.0 - 110.0% | 100.8% (RSD=1.2%, n=6,) | **COMPLIES** |

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

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| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 26/08/2016 |
| **ANALYST:** | 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 |