**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/108

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYDAWA CLINDAMYCIN 300 mg CAPSULES | | **REF. NO: NDQD2016061205** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each hard gelatin Capsule contains Clindamycin Hydrochloride BP equivalent to Clindamycin 300 mg | |
| **BATCH NO.:** R1316 | **PRESENTATION:** | Hard gelatin capsules with an off white coloured body and a blue coloured cap, filled with an off white coloured, free flowing powder, 10 capsules packed in a blister strip 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 Weight, Identification, Disintegration, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 7.5% from mean weight | None Deviates | **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 6.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's In house method | All capsules disintegrate within 30 minutes | All capsules disintegrated within 6 minutes | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In house method | 90.0 - 110.0% | 93.6%, ( RSD=0.8%, n=6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 02/09/2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 02/09/2016 |
| **DIRECTOR** | DR. E. K. CHEPKWONY | .......................................................... | DATE: 02/09/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |