**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/266

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| **PRODUCT** | TRAMADOL CAPSULES BP 50 mg | | **REF. NO: NDQD201605943** |
| **DATE RECEIVED:** 12-05-2016 | **LABEL CLAIM:** | Each hard gelatin capsule contains: Tramadol Hydrochloride BP 50 mg. | |
| **BATCH NO.:** WP402 | **PRESENTATION:** | Hard gelatin capsules with green coloured cap and body filled with an off white powder,packed in a blister strips in a printed box containing 10 strips of 10 capsules each. | |
| **MFG. DATE:** Aug. 2014 | **MANUFACTURER:** | TRIVENI Formulations Limited. | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | Plot No. 52, ALEAP Industrial Estate, Surampalli, A.P., INDIA - 521 212. | |
| **CLIENT REF NO:** | **CLIENT:** | Aiveen (K) Ltd. P. O. BOX 41601 - 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 | B.P. 2016 Vol. V App. XII C | NMT 2 capsule content weights deviate by more than 10% from mean capsule content weight and none deviates by more than 20% from the mean capsule content weight. | Five (5) Deviate (-28%, -11%, -11%, +11%, +21%) | **DOES NOT COMPLY** |
| **Identification** | HPLC | Adopted 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 5.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No Capsule Less Than 75.0% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 92.3%, Range |  |
| **Dissolution** |  |  |  | 92.3 - 92.4%, (RSD=0.1%; n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0% | 96.8% (RSD=1.8%; n=9) | **COMPLIES** |

**CONCLUSION:** The product fails to comply with the specifications for uniformity of weight.

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| **ANALYST:** | MR. MICHAEL SANGALE | .......................................................... | DATE: 11-10-2016 |
| **ANALYST:** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |