**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/287

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | STODIL CAPSULES | | **REF. NO: NDQD201605936** |
| **DATE RECEIVED:** 12-05-2016 | **LABEL CLAIM:** | Each capsule contains: Loperamide hydrochloride USP 2 mg. | |
| **BATCH NO.:** DZ 502 | **PRESENTATION:** | Hard gelatin capsules with a green coloured cap and a yellow coloured body both imprinted with the manufacturer's logo filled with an off white powder, packed in a blister strip of 10 capsules and 10 such strips in a printed box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | TRIVENI Formulations Limited | |
| **EXP. DATE:**  May 2018 | **ADDRESS:** | Plot No. 52, ALEAP, Industrial estate, Surampalli, A.P. - 521 212, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | Aiveen (K) Ltd. P.O BOX 41601- Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 capsule content weights deviate by more than 10% from mean capsule content weight | Two Deviate (-12%, -11%) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4126 | Retention time of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4126 | S2; Average not less than 80% and no unit less than 65%, (n=12) | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 86% (Range |  |
| **Dissolution** |  |  |  | 78 - 91%) (RSD=5.5%; n=12) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4126 | 90.0 - 110.0% | 96.1% (RSD=1.0%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 06-22-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-13-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |