**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/178

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TRICIP 500 mg TABLETS | | **REF. NO: NDQD201605945** |
| **DATE RECEIVED:** 12.05.2016 | **LABEL CLAIM:** | Each film coated tablet contains Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin 500 mg. | |
| **BATCH NO.:** RQ 502 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a blister pack of 10 tablets and 10 such strips in a printed box . | |
| **MFG. DATE:** Apr. 2015 | **MANUFACTURER:** | TRIVENI Formulations Limited. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | Plot No. 52, ALEAP Industrial Estate, Surampali, A.P., 521 212, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Aiveen (K) Ltd., P.O Box 41601-00100-Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, 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 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2824 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2824 | NLT 85% | Average = 92% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89 - 95% , (RSD=2.8%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2824 | 90.0 - 110.0% | 109.4% (RSD=1.8%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR.E .MUTUA | .......................................................... | DATE: 07-09-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 07-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |