**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/177

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ERYMAC 500 TABLETS | | **REF. NO: NDQD201605939** |
| **DATE RECEIVED:** 12-05-2016 | **LABEL CLAIM:** | Each film coated tablet contains Erythromycin stearate BP equivalent to 500 mg Erythromycin. | |
| **BATCH NO.:** BN506 | **PRESENTATION:** | Pink coloured, caplet shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 10 tablets and 10 such blisters in a printed box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | TRIVENI Formulations Limited. | |
| **EXP. DATE:**  Jul. 2018 | **ADDRESS:** | Plot No. 52, Aleap, Industrial eastate, 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, Microbial Assay, Identification, Dissolution | |

**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** | TLC | USP 38 NF 33 page 3362 | The RF value of the principal spot obtained from the sample solution corresponds to that obtained from the Standard solution. | Principle spot at RF value 0.78 +/- 5% obtained from both the sample and standard solutions. | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 page 3362 | No tablet less than 80% [n=6] | Average = 95% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 86 - 97% (RSD=4.4%; n=6) |  |
| **Microbial Assay** | Microbial Assay | USP 38 NF 33 page 3362 | 95.0 - 105% | 105.0% (RSD=1.7%; n=6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | ERIC NGAMAU | .......................................................... | DATE: 06-27-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |