**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/221

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| **PRODUCT** | ERYMAC 250 mg TABLETS | | **REF. NO: NDQD201605938** |
| **DATE RECEIVED:** 12.05.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Erythromycin stearate BP equivalent to 250 mg Erythromycin. | |
| **BATCH NO.:** BR 508 | **PRESENTATION:** | Pink coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 10 tablets and 10 such blisters packed in a printed box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | TRIVENI Formulations Limited. | |
| **EXP. DATE:**  Jul. 2018 | **ADDRESS:** | Plot No. 52, ALEAP, Industrial Estate, Surampalli, A.P., 521 212, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Aiveen (K) Ltd., P.O Box 41601-00100-Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Microbial Assay, Identification, Dissolution | |

**RESULTS**

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| **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 0.74 +/- 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 | **COMPLIES** |
| **Dissolution** |  |  |  | 84% Range |  |
| **Dissolution** |  |  |  | 83%-85% (RSD=0.6%; n=6) |  |
| **Microbial Assay** | Microbial Assay | USP 38 NF 33 Page 3362 | 90.0 - 120.0% | 100.9% (RSD=1.8%, n=6) | **COMPLIES** |

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

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 18-07-16 |
| **ANALYST** | DR. E. TANUI | .......................................................... | DATE: 19-07-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-02-2016 |