**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/731

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE & ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | REF. NO: NDQB201604888 |
| **DATE RECEIVED:** 28.04.2016 | **LABEL CLAIM:** | Each film coated tablet contains 150 mg of Lamivudine USP, 200 mg of Nevirapine USP and 300 mg of Zidovudine USP. | |
| **BATCH NO.:** LZV16016 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed '3' on one face and 'H' on the other face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | Unit-V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.1, 4.4 and 6.7 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | Lamivudine 99.9% (RSD=2.9%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | Nevirapine 97.4% (RSD=1.1%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | Zidovudine 96.8% (RSD=2.8%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90% - 110% | Lamivudine 99.30% (RSD=0.2%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90% - 110% | Nevirapine 95.1% (RSD=0.4%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90% - 110% | Zidovudine 97.4% (RSD=0.2%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Uniformity of Weight** |  | B.P. 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:23-05-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:08-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-14-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-16-2016 |