**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/56

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE & ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQB2016061179** |
| **DATE RECEIVED:** 16-06-2016 | **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.:** LZV16032 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed '3' on one face and 'H' on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Mar. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Feb. 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** |
| **Uniformity of Weight** | Weight | BP 2016 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | 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 3.0, 4.2 and 7.2 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Lamivudine Average = 104% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 103-104% (RSD=0.7%, n=6) |  |
| **Dissolution** |  |  |  | Nevirapine Average = 93% Range |  |
| **Dissolution** |  |  |  | 93-94% (RSD=0.8%, n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average = 95% Range |  |
| **Dissolution** |  |  |  | 94-96% (RSD=0.7%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 91.6% (RSD=0.7% n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 100.5% (RSD=0.5%, n=6) |  |
| **Assay** |  |  |  | Zidovudine 102.4% (RSD=0.4%, n=6) |  |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 06-07-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 08-08-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-17-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-18-2016 |