**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/33

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE and ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQB2016061160** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each film coated tablets contains 150 mg of Lamivudine USP, 200 mg of Nevirapine USP and 300 mg of Zidovudine USP. | |
| **BATCH NO.:** LZV114021 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed on one face and '3' on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Dec. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | Unit- V. APIIC Formulation SEZ, Polepally village, Jadcherla Mandal, Mahabood Nagar (Dist) - 509301, Andhra Pradesh, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority P.O. Box 47715 - 00100, Nairobi, KENYA. | |
| AZT/3TC/NVP/25/05/2016/144 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 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 2.9, 3.9 & 6.8 Â± 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 106%, Range 105% - 106%, (RSD=0.5%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average 99%, Range 95% - 101%, (RSD=2.2%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine 95.6%, Range (95% - 96%), (RSD=0.3%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In - house Method | 90-110% | Lamivudine 96.6%, (RSD=0.4%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 100.0%, (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | zidovudine 92.9%, (RSD=0.5%, n=6) | **COMPLIES** |

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

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-20-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |