**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/440

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE and ZIDOVUDINE TABLETS 150 mg/ 200 mg / 300 mg | | REF. NO: NDQB201601686 |
| **DATE RECEIVED:** 26.01.2016 | **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.:** LZV114010 | **PRESENTATION:** | White coloured, caplet-shaped, biconvex faced tablets, embossed 'H' on one face and '3' on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Oct. 2014 | **MANUFACTURER:** | HETERO Labs limited. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | Unit-V, APIIC Formulation SEZ, Polepally Village, Jadcherla (Mandal), Mahaboob Nagar (District), Pin-509301, Andhra Pradesh, 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 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 standard preparation | Super-imposable peaks at RT 3.2, 4.3 and 7.1 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Lamivudine 107.1% (RSD=1.6%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Nevirapine 105.0% (RSD=1.5%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Zidovudine 105.5% (RSD=1.1%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 108.5% (RSD=0.8%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Nevirapine 108.6% (RSD=1.1%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Zidovudine 108.1% (RSD=0.7%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:29-02-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:14-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-22-2016 |