**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/43

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE and ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQB201604884** |
| **DATE RECEIVED:** 2016-04-26 | **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.:** LZV16003 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex tablets, embossed â€˜Hâ€™ on one face and '3' on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. 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** |
| **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 assay standard preparation | Super-imposable peaks at RT 2.9, 3.9 & 6.8 ± 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 101%, Range 100% - 104% (RSD=1.7%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average 102%, Range 100% - 105% (RSD=1.6%, n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average 93% Range 92% - 96% (RSD=1.5%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | Lamivudine 98.2% (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 98.5% (RSD=0.8%, n=9) |  |
| **Assay** |  |  |  | zidovudine 94.1% (RSD=0.6, n=9) |  |

**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 |