**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/183

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQD2016061049** |
| **DATE RECEIVED:** 03-06-2016 | **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.:** LZV115002 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed â€˜3â€™ on one face and â€˜Hâ€™ on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Dec. 2017 | **ADDRESS:** | Unit - V, APIIC Formulation SEZ, Polepally village, Jadcherla Mandal, Mahaboob Nagar (Dist) - 509301, Andhra Pradesh, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| 3TC/NVP/AZT/01/07.03.2016/0009 | **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 Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 3.0, 4.2 & 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% | Lamivudine Average 101% Range 100 - 102% (RSD=0.6%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average = 98%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 98 - 99%, (RSD=0.7%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine Average = 94% Range |  |
| **Dissolution** |  |  |  | 93 - 95%, (RSD=0.6%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | Lamivudine 90.5% (RSD=2.0%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 97.8% (RSD=1.8%; n=9) |  |
| **Assay** |  |  |  | Zidovudine 96.0% (RSD=1.7%; n=8) |  |

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

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 07-01-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 05-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |