**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/32

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| **PRODUCT** | LAMIVUDINE 150 mg, ZIDOVUDINE 300 mg & NEVIRAPINE 200 mg TABLETS | | **REF. NO: NDQD2016061043** |
| **DATE RECEIVED:** 2016-06-03 | **LABEL CLAIM:** | Each tablets contains: Lamivudine USP 150 mg, Zidovudine USP 300 mg and Nevirapine USP 200 mg | |
| **BATCH NO.:** BLE7510A | **PRESENTATION:** | Off white coloured, ovoid shaped, biconvex faced tablets, embossed â€˜ML 20™ on one face and plain on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | Village Theda, P. O. Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh - 174101, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| AZT/3TC/NVP/10/08.03.2016/0057 | **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 3.0, 4.2 & 7.2 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 105%, Range 104% - 107%, (RSD=1.0%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine Average 94%, Range 93% - 95%, (RSD=0.7%, n=6) |  |
| **Dissolution** |  |  |  | Nevirapine Average 88%, Range 82% - 92%, (RSD=3.9%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | Lamivudine 90.4%, (RSD=0.6%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 96.9%, (RSD=1.0%, n=6) |  |
| **Assay** |  |  |  | Nevirapine 100.0%, (RSD=0.8%, n=6) |  |

**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 |