**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/36

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE & ZIDOVUDINE TABLETS 150 mg/ 200 mg/ 300 mg | | **REF. NO: NDQD2016061047** |
| **DATE RECEIVED:** 2016-06-03 | **LABEL CLAIM:** | Each film - coated tablets contains Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 7224025 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex FACED tablets, embossed on one face and plain on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Mar. 2015 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | S/No. 36/7 Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bangalore - 562 106, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| 3TC/NVP/AZT/10/11.03.2016/0119 | **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 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 ± 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 99%, Range 98% - 100%, (RSD=0.7%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average 93.1%, Range 88% - 95%, (RSD=2.7%, n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average 91%, Range 90% - 92%, (RSD=1.1%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90-110 | Lamivudine 94.5%, (RSD=1.9%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 95.0%, (RSD=1.8%, n=9) |  |
| **Assay** |  |  |  | Zidovudine 91.8%, (RSD=1.8, 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 |