**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/655

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE & ZIDOVUDINE TABLETS 150 mg/ 200 mg/ 300 mg | | REF. NO: NDQB201603804 |
| **DATE RECEIVED:** 15.03.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 7224183 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed 'ZLN' on one face and plain on the other face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | S-No. 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bangalore - 562 106, 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 3.7, 4.6 and 6.3 -/+ 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 98.0% (RSD=3.5%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Nevirapine 95.0% (RSD=3.5%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Zidovudine 96.0% (RSD=4.0%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 100.6% (RSD=0.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Nevirapine 97.8% (RSD=0.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Zidovudine 98.2% (RSD=0.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:16-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-23-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |