**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/328

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 mg | | **REF. NO: NDQB201610160** |
| **DATE RECEIVED:** 11.10.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: 300 mg of Tenofovir Disoproxil Fumarate equivalent to 245 mg of Tenofovir Disoproxil. | |
| **BATCH NO.:** 7227514 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, embossed™ on one face and plain on the other, packed in a white, plastic, multi-dose container of 30 tablets contained in a printed box. | |
| **MFG. DATE:** Jun. 2016 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:**  May 2018 | **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** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-house Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-house Method | No tablet less than 80.0% | 98.9% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 98 - 99%) (RSD=0.5%; n=6) |  |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | 99.2% (RSD=1.1%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 10-26-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 30-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-30-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |