**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/437

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| **PRODUCT** | VIREAD(TM) superscript without brackets TABLETS | | REF. NO: NDQB201601713 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains 300 mg of Tenofovir Disoproxil Fumarate, which is equivalent to 245 mg of Tenofovir Disoproxil. | |
| **BATCH NO.:** D273375M | **PRESENTATION:** | Off white coloured, tear drop shaped, biconvex faced tablets, embossed 'GILEAD 4331' on one face and plain on the other, packed in a white plastic multidose container with a childproof cap carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | TAKEDA GmbH. | |
| **EXP. DATE:**  Aug. 2019 | **ADDRESS:** | 16515 Oranienburg, GERMANY. | |
| **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 peak at RT 15.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Tenofovir 107.1% (RSD=1.7%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir 98.8% (RSD=0.2%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:29-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:07-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-10-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-15-2016 |