**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/3

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| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | **REF. NO: NDQB2016061149** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each film-coated tablet contains: Lamivudine USP 300 mg and Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg. | |
| **BATCH NO.:** LTSA15005-A | **PRESENTATION:** | Blue coloured, caplet shaped, biconvex tablets, embossed â€˜Jâ€™ on one face and â€˜27â€™ on the other, 30 tablets packed in a plastic multidose container with a child proof lid in a unit box. | |
| **MGF. DATE:** Apr 2015 | **MANUFACTURER:** | Aurobindo Pharma Limited | |
| **EXP. DATE:**  Mar 2017 | **ADDRESS:** | Unit - VII, SEZ, APIIC, Plot No. S1, S. No's: 411, 425, 434, 435 & 458, Green Industrial Park, Polepally Village. Jedcherla Mandal, Mahaboobnagar District, Andhra Pradesh, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority P.O. Box 47715 - 00100, Nairobi, KENYA. | |
| TDF/3TC/24/05/2016/130 | **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 Major Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.0 & 5.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80 % | Lamivudine Average = 88% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 84% - 90% (RSD=2.4%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Tenofovir Disiproxil Fumarate Average = 96% Range |  |
| **Dissolution** |  |  |  | 95% - 97% (RSD=0.9%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90 % - 110% | Lamivudine 97.2% (RSD=1.8%, n=7) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir Disiproxil Fumarate 94.0% (RSD=0.3%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-26-2016 |