**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | FORSTAVIR-LE TABLETS | | REF. NO: NDQD201509266 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Efavirenz USP 600 mg, Lamivudine USP 300 mg, Tenofovir disoproxil fumarate 300 mg equivalent to Tenofovir disoproxil 245 mg. | |
| **BATCH NO.:** EISA15024-A | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed '91' on one face and 'I' on the other, packed in a white plastic multi-dose container carrying 30 tablets 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. Nos: 411, 425, 434 & 458, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar District, Telangana State, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Simba Pharmaceuticals Limited P.O.Box 1541 - 00600, Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC:HPLC: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 | **COMPLIES** |
| **Identification** | HPLC:HPLC:HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | 7.3, 16.8 and 25.6 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] No tablet less than 85.0% [n=6] No tablet less than 85.0% [n=6] | Efavirenz 99.1%, (n=6; RSD=1.6%) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] No tablet less than 85.0% [n=6] No tablet less than 85.0% [n=6] | Lamivudine 104.5% (RSD=2.2%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] No tablet less than 85.0% [n=6] No tablet less than 85.0% [n=6] | Tenofovir Disoproxil 95.6%, (n=6; RSD=3.0%) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0% -110.0 % | Efavirenz 106.0%, (n=9; RSD=0.6%) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0% -110.0 % | Lamivudine 106.2%, (n=9; RSD=0.7%) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0% -110.0 % | Tenofovir Disoproxil 97.0%, (n=9; RSD=1.7%) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:02-11-2015 |
| REVIEWER: | DR. G. WANG’ANG’A |  | DATE:04-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-05-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-09-2015 |