**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/64

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| **PRODUCT** | FORSTAVIR-3 TABLETS | | **REF. NO: NDQD201509265** |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Efavirenz USP 600 mg, Emtricitabine 200 mg and Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg. | |
| **BATCH NO.:** EKSA15001-A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed â€˜I48â€™ on one face and plain on the other, 30 tablets packed in a plastic multidose container fitted with a childproof lid a unit box. | |
| **MFG. DATE:** Mar. 2015 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | Unit-VII, SEZ, APIIC, Plot. No. S1, S. Noâ€™s: 411, 425, 434, 435 & 458, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar District, Telangana State, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Simba Pharmaceuticals Limited P. O. Box 1541 - 00606, 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 standard preparation | Super-imposable peaks at RT 4.1, 15.8 and 17.1-/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85% (n=6) | Efavirenz Average = 97% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 88 - 102% (RSD=4.9%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Emtricitabine Average 94% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89 - 98% (RSD=3.4%, n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 99% Range |  |
| **Dissolution** |  |  |  | 93 - 104% (RSD=4.6%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 105.0% | Efavirenz 100.2% (RSD=1.2%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Emtricitabine 98.0% (RSD=1.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 101.6% (RSD=1.6%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. L .KARANJA | .......................................................... | DATE: 24/08/2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 24/08/2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 24/08/2016 |