**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/114

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| **PRODUCT** | AVIRODAY - EM TABLETS | | **REF. NO: NDQD201508173** |
| **DATE RECEIVED:** 18.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains Efavirenz 600 mg, Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg. | |
| **BATCH NO.:** 14EL001D | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'RF 21' on one face and plain on the other, packed in a childproof-lid plastic multidose container of 30 tablets and contained in a unit box. | |
| **MFG. DATE:** Jul. 2014 | **MANUFACTURER:** | SHASUN Pharmaceuticals Limited. | |
| **EXP. DATE:**  Jun. 2016 | **ADDRESS:** | RS NO.32,33 and 34, Shasun Road Periyakalapet, Puducherry-605 014 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | SUN Pharma EAST Africa Ltd. P.O. Box | |
|  | **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 | Manufacturer's 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 3.2, 14.3 and 16.0 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 85% (n=6) | Efavirenz Average = 89% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 86 - 96% (RSD=4.5%, n=6) |  |
| **Dissolution** |  |  |  | Emtricitabine Average = 92% Range |  |
| **Dissolution** |  |  |  | 90 - 94% (RSD=1.6%,n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average 91% Range 88% - 98% (RSD=4.6%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 - 105.0% | Efavirenz 96.5% (RSD=0.7%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Emtricitabine 109.2% (RSD=1.0%, n=6) |  |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 96.3% (RSD=1.4%, n=6) |  |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 24/08/2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 13-06-2016 |
| **DIRECTOR:** | DR.H. K. CHEPKWONY | .......................................................... | DATE: 08-24-2016 |