**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | DOLUTEGRAVIR 50mg TABLETS | | REF. NO: NDQD201507028 |
| **DATE RECEIVED:** 16.07.2015 | **LABEL CLAIM:** | Each film-coated tablets contains Dolutegravir sodium equivalent to Dolutegravir 50mg. | |
| **BATCH NO.:** DUSA14001-A | **PRESENTATION:** | Brick red coloured, round shaped, biconvex faced tablets, embossed 'T50' on one face and plain on the other , packed in a white plastic multi dose container carrying 30 tablets fitted with a child proof screw cap in a unit box. | |
| **MGF. DATE:** Jul.2014 | **MANUFACTURER:** | Aurobindo Pharma Limited. | |
| **EXP. DATE:** Jun.2016 | **ADDRESS:** | Unit VII,SEZ,APIIC, Plot No. S1, S.No's 411, 425, 434, 435 and 458, Green Industrial Park PolePally Village, Jedcherla Mandal, Mahoboobnagar 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 x% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's Method; MOA 1487 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's Method; MOA 1487 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | 5.9 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | Manufacturer's Method; MOA 1487 | No tablet less than 85% | 99.1% (RSD = 1.1% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC:HPLC | Manufacturer's Method; MOA 1487 | 90.0-110.0% | 99.7% (RSD = 0.7% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:09-03-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE: |
| ANALYST: | SERAH MUTERU |  | DATE:10-07-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-09-2015 |