**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | EFAVIRENZ 600MG TABLETS | | REF. NO: NDQD201504193 |
| **DATE RECEIVED:** 2015-04-22 | **LABEL CLAIM:** | Each film-coated tablet contains Efavirenz 600mg | |
| **BATCH NO.:** HG6014001-A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed '37' on one face and 'D' on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Sep.2014 | **MANUFACTURER:** | Aurobindo Pharma LImited. | |
| **EXP. DATE:** Aug.2017 | **ADDRESS:** | Unit III, Survey No.313, Bachupally Village, Quthubullapur Mandal. Ranga Reddy District (A.P), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Chemonics Kenya Pharma LLC P.o Box 1325 00606 Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, 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 | Adopted In House Method | RT of the component Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value 19.9 +- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Identification** | HPLC | Adopted In House Method | RT of the component Peak in the assay sample preparation corresponds to that in the assay standard preparation |  | **COMPLIES** |
| **Friability** | Friability | B.P. 2012 Vol V App. XVII G. | NMT 1% | 0.03% | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In House Method | No tablet less than 80% | efavirenz 100.5%(RSD = 3.9% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In House Method: | 90-110% | efavirenz 95.9%(RSD = 1.4% ; n = 8) | **COMPLIES** |

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

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| ANALYST: | DR. K. HASSAN |  | DATE:14-05-2015 |
| ANALYST: | DR. E. MBAE |  | DATE:19-08-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:19-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:08-26-2015 |