**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ABACAVIR SULFATE TABLETS 300 mg | | REF. NO: NDQD201508133 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** AB3013011-A | **PRESENTATION:** | Yellow coloured, caplet shaped tablets, engraved 'D' on one face and '88' on the opposite face, packed in a white coloured, plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2013 | **MANUFACTURER:** | Aurobindo Pharma LImited. | |
| **EXP. DATE:** Mar. 2016 | **ADDRESS:** | Unit III, Survey No. 313, Bachupally Village, Quthubullapur Mandal, Ranga Reddy District (A. P.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | 7.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | U.S.P 38 NF 33 Vol 2 Page 1997 | No tablet less than 85.0% [n=6] | 99.0% (RSD=1.9%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% | 100.9% (RSD=0.6%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-05-2015 |