**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | HEPTAVIR - 150 TABLETS | | REF. NO: NDQD201508124 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg. | |
| **BATCH NO.:** E141003 | **PRESENTATION:** | Brown colored, caplet shaped, biconvex faced tablets, single scored on one face and embossed 'H' and 'V' on either side of the score and '150' on the opposite unscored face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:** May 2017 | **ADDRESS:** | 22 - 110, I.D.A., Jeedimetla, Hyderabad - 500 055, 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 2.9 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | 97.9% (RSD = 4.9%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 103.7% (RSD = 0.7%; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:01-10-2015 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:19-10-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-05-2015 |