**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/289

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| **PRODUCT** | HEPTAVIR - 150 TABLETS | | **REF. NO: NDQD201606997** |
| **DATE RECEIVED:** 02-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg. | |
| **BATCH NO.:** E141005 | **PRESENTATION:** | Brown coloured, caplet shaped, biconvex faced tablets, single scored and embossed 'H' and 'V' on alternate sides of the scored on one face and '150' on the other, 60 such tablets packed in a sealed plastic container in a printed box. | |
| **MFG. 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 - 00202, Nairobi, KENYA. | |
| 3TC/05/09.03.2016/0078 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 tablets deviate by more than 5% from mean tablet weight | One deviates (-6%) | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Page 753 | Retention time of the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | BP 2016 Page 753 | No tablet less than 80% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 93% (Range |  |
| **Dissolution** |  |  |  | 92 - 93%) (RSD=0.4%; n=6) |  |
| **Assay** | HPLC | BP 2016 Page 753 | 95.0 - 105.0% | 101.1% (RSD=0.5%; n=9) | **COMPLIES** |

**CONCLUSION:**

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| **NULL** | NULL | .......................................................... | DATE: null |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |