**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LAMIVUDINE / ZIDOVUDINE TABLETS 30 mg/60 mg | | REF. NO: NDQD201508165 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 30 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 3014751 | **PRESENTATION:** | White coloured, film coated, circular shaped tablets, single scored on one face and embossed 'M29' on the opposite, unscored face, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jun. 2013 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:** May 2015 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, Maharashtra, 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 | |

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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 7.5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC:HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.8 and 3.7 Ã‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Lamivudine | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | 95.6% (RSD = 3.3%; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Zidovudine | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | 98.5% (RSD = 4.3%; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | 97.0% (RSD = 1.3% ; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | Zidovudine | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | 96.1% (RSD = 1.7% ; n = 9) | **COMPLIES:COMPLIES** |

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

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