**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LAMIVUDINE/ZIDOVUDINE DISPERSIBLE TABLETS 30 mg/60 mg | | REF. NO: NDQD201508161 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each dispersible tablet contains: Lamivudine USP 30 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 3029719 | **PRESENTATION:** | 0ff white colored, circular shaped, biconvex faced tablet, single scored on one face and embossed "LZ" and '1' on either side of the score on one face and "M" on the opposite unscored face packed in a white plastic multidose container carrying 60tablets in a unit box | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:** Jul. 2016 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, 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 Values | **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 | 2.9 and 3.8 Â± 10% min. present in the sample preparation | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Lamivudine | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | 92.8% (RSD = 5.6%; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Zidovudine | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | 97.4% (RSD = 5.9%; 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% | 94.9% (RSD = 1.8%; 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% | 94.1% (RSD = 0.6%; n = 9) | **COMPLIES:COMPLIES** |

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

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