**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE  DISPERSIBLE TABLETS 30 mg/50 mg/60 mg | | **REF. NO:** NDQD2016061061 |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each dispersible tablet contains Lamivudine USP 30 mg, Nevirapine USP 50 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 3010273 | **PRESENTATION:** | Faint yellow coloured, circular shaped, flat-faced, bevel-edged tablets, single scored and embossed ΄M09΄ on one side of the score on one face and plain on the opposite, unscored face, packed in a white, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Mar. 2013 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:** Feb. 2017 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj,  Aurangabad - 431136, Maharashtra,  INDIA. | |
| **CLIENT REF NO:**  AZT/3TC/NVP/  04/8.03.2016/0021 | **CLIENT:** | National AIDS and STI Control Program,  P. O. Box 19361-00202, KNH, Nairobi,  KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Disintegration, Friability and Assay. | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 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 component peaks in the sample assay preparation correspond to those in the standard assay preparation | Super-imposable peaks at  RT 3.0, 4.2 and 7.6 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Friability** | Weight | BP 2016 Vol. V  App XVII G | Not more than 1% | 0.02% | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V  App XII A | All tablets disintegrate within 3 minutes [n=6] | Tablets disintegrated within 3 minutes | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | **Zidovudine:** 95.0% (RSD=0.9%; n=9) | **COMPLIES** |
| **Nevirapine:** 102.6%  (RSD=1.5%; n=9) | **COMPLIES** |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ANALYST:** | MS. S. MUTHONI |  | DATE: | 22-05-2017 |
| **ANALYST:** | DR. N. MWAURA |  | DATE: | 22-05-2017 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | DATE: | 22-05-2017 |

|  |
| --- |
| **INVOICE** |

|  |  |
| --- | --- |
| **INVOICE No: /16-17** | **Date: 22nd May 2017** |

|  |
| --- |
| **National AIDS and STI Control Program,** |
| **P.O. Box 19361 – 00202, KNH, Nairobi,** |
| **KENYA.** |

**Re: ANALYSIS OF LISTED PRODUCT**.

|  |  |
| --- | --- |
| **PRODUCT:** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE  DISPERSIBLE TABLETS 30 mg/50 mg/60 mg |
| **BATCH NO:** | 3010273 |
| **CERTIFICATE NO:** | CAN/2016-17/ |
| **LABORATORY REF NO:** | NDQD2016061061 |
| **CLIENT REF NO:** | AZT/3TC/NVP/04/8.03.2016/0021 |
| **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Disintegration, Friability and Assay. |

**COST OF ANALYSIS:**

|  |  |  |  |
| --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **COST (KShs)** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V | **2,040.00** |
| **Friability** | Weight | BP 2016 Vol. V | **4,080.00** |
| **Disintegration** | Disintegration | BP 2016 Vol. V | **4,800.00** |
| **Identification and Assay** | HPLC | Adopted In-House Method | **52,630.00** |
|  | | **TOTAL COST** | **63,550.00** |
| **DISCOUNT 5%** | **(3,177.50)** |
| **AMOUNT PAYABLE** | **60,372.50** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE:** | 22/05/2017 |