**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/457

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE DISPERSIBLE TABLETS 30 mg/50 mg/60 mg | | REF. NO: NDQB201601683 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each dispersible tablet contains: Lamivudine USP 30 mg, Nevirapine USP 50 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 13HD001B | **PRESENTATION:** | Beige coloured, circular shaped, flat faced, bevel edged tablets, single scored one face and embossed 'M09' on one side of the score and plain on the other face. Packed in a white coloured, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** May 2013 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Apr. 2018 | **ADDRESS:** | R. S. No. 32, 33 & 34, Shasun Road, Periyakalapet, Puducherry ÃƒÆ’Ã‚Â¢ÃƒÂ¢Ã¢â‚¬Å¡Ã‚Â¬ÃƒÂ¢Ã¢â€šÂ¬Ã…â€œ 605 014, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
| 42 NYERI PGH | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Disintegration, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In- House Method | RT of the component Peaks in the assay sample preparation correspond to those in the standard preparation | Super-imposable peaks at RT 3.2, 4.3 and 6.4 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App XII A | No tablet more than 3 min [n=6] | Water | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App XII A | No tablet more than 3 min [n=6] | All < 2 minutes | **COMPLIES** |
| **Assay** | HPLC | Adopted In- House Method | 90.0 - 110.0% | Lamivudine 101.0% (RSD=2.0%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In- House Method | 90.0 - 110.0% | Nevirapine 103.7% (RSD=1.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In- House Method | 90.0 - 110.0% | Zidovudine 102.9% (RSD=0.6%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:29-02-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:14-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-29-2016 |