**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/458

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| **PRODUCT** | LAMIVUDINE and ZIDOVUDINE TABLETS FOR ORAL SUSPENSION 30 mg/ 60mg | | REF. NO: NDQB201601675 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each uncoated tablet for oral suspension contains Lamivudine USP 30 mg Zidovudine USP 60 mg. | |
| **BATCH NO.:** X40871 | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced, bevel edged tablets, single scored one face and embossed 'DR' plain on the other face. Packed in a white coloured, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Oct. 2014 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Sep. 2016 | **ADDRESS:** | Verna, Indl. Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **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 7.5% 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 and 4.3 -/+ 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] | All < 2 minutes | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | lamivudine 103.7% (RSD=0.9%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Zidovudine 102.3% (RSD=0.9%, n=9) | **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:14-03-20116 |
| ANALYST: | ERNEST MBAE |  | DATE:03-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-31-2016 |