**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/651

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| **PRODUCT** | ZIDOVUDINE TABLETS USP 300 mg | | REF. NO: NDQB201603827 |
| **DATE RECEIVED:** 31.03.2016 | **LABEL CLAIM:** | Each film-coated contains 300 mg of Zidovudine USP. | |
| **BATCH NO.:** E132266 | **PRESENTATION:** | Off-white coloured, circular shaped, biconvex faced tablets, embossed 'H' on one face and '1' on the other, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Dec. 2013 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Nov. 2016 | **ADDRESS:** | 22-110, I.D.A., Jeedimetla, Hyderabad - 500 055, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, 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 tablets weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.7 -/+ 10% min for Zidovudine present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | 98.0% (RSD=1.7%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | 99.3% (RSD=0.8%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:16-05-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |