**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/415

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201601703 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains Nevirapine USP 200 mg. | |
| **BATCH NO.:** G44506 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'N ' on the other face, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** May 2014 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | Verna Industrial Estate. Gao 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, 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 tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 2015 Page 4540 | RT of the major Peak in the sample preparation corresponds to those in the standard preparation | Super-imposable peak at RT 9.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 2015 Page 4540 | No tablet less than 80.0% [n=6] | 88.81% (RSD=4.06%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 2015 Page 4540 | 90.0 - 110.0% | 98.01% (RSD=0.73%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:19-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:01-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-04-2016 |