**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/704

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| **PRODUCT** | LOPINAVIR and RITONAVIR ORAL PELLETS 40 mg/10 mg | | REF. NO: NDQD201602760 |
| **DATE RECEIVED:** 18.02.2016 | **LABEL CLAIM:** | Each capsule contains: Lopinavir USP 40 mg and Ritonavir USP 10 mg. | |
| **BATCH NO.:** GG51956 | **PRESENTATION:** | Hard gelatin capsules with a yellow coloured cap and a clear body, filled with white pellets, packed in a white plastic multi-dose container carrying 120 capsules in a unit box. | |
| **MGF. DATE:** Oct. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | Verna Indl. Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **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 capsules deviate by more than 10% from mean capsule weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the component peaks in assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 7.0 & 8.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | : S2: Average Not Less Than 80%; No Unit Less Than 65% (n=12) |  | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | : S2: Average Not Less Than 80%; No Unit Less Than 65% (n=12) |  | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | : S2: Average Not Less Than 80%; No Unit Less Than 65% (n=12) | Lopinavir 89.9% (RSD=5.3%, n=12) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | : S2: Average Not Less Than 80%; No Unit Less Than 65% (n=12) | Ritonavir 87.1% (RSD=4.8%, n=12 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0% - 110.0% | Lopinavir 102.9% (RSD=0.2%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0% - 110.0% | Ritonavir 97.9% (RSD=0.2%, n=9 | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:12-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:06-03-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-07-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-10-2016 |