**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/157

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| **PRODUCT** | DARUNAVIR (AS ETHANOLATE) TABLETS 800 mg | | **REF. NO: NDQD201608060** |
| **DATE RECEIVED:** 04-08-2016 | **LABEL CLAIM:** | Each film - coated tablet contains Darunavir (as ethanolate) equivalent to Darunavir 800 mg. | |
| **BATCH NO.:** PB60664 | **PRESENTATION:** | Brick Red coloured, Ovoid shaped, biconvex faced tablets, imprinted â€˜DNVâ€™ on one face and â€˜800â€™ on the other, 30 tablets packed in a white plastic multidose container fitted with a childproof lid in a printed box. | |
| **MFG. DATE:** Dec. 2014 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Nov. 2016 | **ADDRESS:** | MIDC Patalganga, M.S 410 220, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd, P.O. Box 49146 - 00100 GPO, 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 | Manufacturer's Method | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value 7.4 ± 10% min. present in the sample preparation | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's Method | No Tablet Less Than 75% | Average = 87% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 86 - 87% (RSD = 0.1%; n = 6) |  |
| **Assay** | HPLC | Manufacturer's Method | 95.0 - 107.5% | 95.4% (RSD = 0.4%; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH KARIUKU | .......................................................... | DATE: 09-06-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 03-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-07-2016 |