**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/286

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| **PRODUCT** | ABACAVIR SULFATE and LAMIVUDINE TABLETS 600 mg /300 mg | | **REF. NO: NDQD201608076** |
| **DATE RECEIVED:** 11-08-2016 | **LABEL CLAIM:** | Each film coated tablet contains Abacavir sulfate equivalent to Abacavir 600 mg and Lamivudine USP 300 mg. | |
| **BATCH NO.:** PA53284 | **PRESENTATION:** | Peach coloured, caplet shaped, biconvex faced tablets embossed 'C' on one face plain on the other, 30 such tablets packed in a sealed plastic container fitted with a childproof lid in a printed box. | |
| **MFG. DATE:** Dec. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Nov. 2017 | **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** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | Retention time of the major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.8 and 4.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 85% | Abacavir Sulfate Average | **COMPLIES** |
| **Dissolution** |  |  |  | 104% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 101 - 107%) (RSD=2.0%; n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average |  |
| **Dissolution** |  |  |  | 101% (Range |  |
| **Dissolution** |  |  |  | 98 - 105%) (RSD=2.9%; n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Abacavir Sulfate 97.3% (RSD=1.6%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 98.7% (RSD=1.5%; n=9) | **COMPLIES** |

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

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| **NULL** | NULL | .......................................................... | DATE: null |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |