**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/285

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| **PRODUCT** | ABACAVIR SULFATE AND LAMIVUDINE TABLETS FOR ORAL SUSPENSION 120 mg/60 mg | | **REF. NO: NDQD201608077** |
| **DATE RECEIVED:** 11-08-2016 | **LABEL CLAIM:** | Each uncoated tablet for oral suspension contains Abacavir Sulfate USP equivalent to Abacavir 120 mg and Lamivudine USP 60 mg. | |
| **BATCH NO.:** PA60577 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on one face and embossed 'C J' on the other, 60 such tablets packed in a sealed plastic container with a child-proof closure in a printed box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Dec. 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, Friability, Dissolution, Disintegration, 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** |
| **Friability** | Weight | Manufacturer's In-House Method | Percentage weight loss NMT 1.0% | 0.01% | **COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's In-House Method | All tablets disintegrate within 3 minutes | All tablets disintegrated within 30 seconds | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | Not tablet less than 85% | Abacavir Sulfate Average | **COMPLIES** |
| **Dissolution** |  |  |  | 108% Range 108 - 109% (RSD=0.4%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Lamivudine Average |  |
| **Dissolution** |  |  |  | 98% (Range |  |
| **Dissolution** |  |  |  | 95 - 101%) (RSD=2.8%; n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Abacavir Sulfate 97.8% (RSD=0.4%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 98.5% (RSD=0.9%; 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: 10-17-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |