**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | LAZIDAVIR(R) PAEDIATRIC TABLETS | | REF. NO: NDQD201509282 |
| **DATE RECEIVED:** 15.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains Lamivudine (3TC) USP 30 mg and Zidovudine (AZT) USP 60 mg. | |
| **BATCH NO.:** E40082 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced, film-coated tablets single scored on one face and embossed 'COSMOS' on the other, packed in a white plastic multi-dose container with a child proof cap carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | COSMOS Limited | |
| **EXP. DATE:** May. 2016 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road, P.O. Box 41433 - 00100, Nairobi, KENYA | |
| **CLIENT REF NO:** | **CLIENT:** | Cosmos Ltd. Lunga Lunga Rd, Rangwe Close, P.O. Box 41433, 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 7.5% from mean weight | 1 Deviates (-11.2%) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Pg 4024 | RT of component peaks in assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 13.5 and 38.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Dissolution Test 2 Pg 4024 | No tablet less than 85% | Lamivudine 102.8% (RSD = 2.3%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Dissolution Test 2 Pg 4024 | No tablet less than 85% | Zidovudine 99.4% (RSD = 1.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33, Pg 4024 | 90.0 - 110.0 % | Lamivudine 99.9% (RSD = 0.3%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33, Pg 4024 | 90.0 - 110.0 % | Zidovudine 100.1% (RSD = 0.3%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | SARAH MWANGI |  | DATE:10-27-2015 |
| REVIEWER: | NICHOLAS MWAURA |  | DATE:11-24-2015 |
| DIRECTOR: | H. K. CHEPKWONY |  | DATE:12-23-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-15-2016 |