**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/652

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE / ZIDOVUDINE TABLETS 150 mg/300 mg | | REF. NO: NDQD201603784 |
| **DATE RECEIVED:** 04.03.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg & Zidovudine USP 300 mg. | |
| **BATCH NO.:** X30676 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed 'DVR' on one face and plain on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jul. 2013 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Jun. 2016 | **ADDRESS:** | Verna Indl. Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | WHO - SOMALIA, WHO-SOMALIA liaison Office, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.4 and 4.7 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Lamivudine 98.0% (RSD=1.9%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Zidovudine 94.0% (RSD=2.5%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 95.8% (RSD=2.0%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Zidovudine 95.6% (RSD=1.1%, n=9) | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:16-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-23-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-23-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |