**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/199

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | FLUCONAZOLE 200 mg TABLETS | | **REF. NO: NDQB201609111** |
| **DATE RECEIVED:** 20-09-2016 | **LABEL CLAIM:** | Each tablet contains: Fluconazole U.S.P. 200 mg. | |
| **BATCH NO.:** 621581 | **PRESENTATION:** | Pink coloured, circular shaped, flat faced, bevel edged tablets, single scored on one face and embossed 'UCL' on the other, packed in a blister packs of 10 tablets and 10 such blisters in a printed box. | |
| **MFG. DATE:** Aug. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Jul. 2019 | **ADDRESS:** | Club Road, Plot No. 13777, P. O. Box 1748 - 00902, Kikuyu, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, 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 Deviate | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 3516 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | None | USP 38 NF 33 page 3516 | No Tablet Less Than 80% | Average = 88% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 81 - 96% (RSD = 6.8%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 3516 | 90.0 - 110.0% | 101.4% (RSD = 0.5%; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 18-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-19-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-19-2016 |