**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/438

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | DICONAZOL-200 TABLETS | | REF. NO: NDQB201602769 |
| **DATE RECEIVED:** 23.02.2016 | **LABEL CLAIM:** | Each film coated tablets contains: Fluconazole 200 mg. | |
| **BATCH NO.:** 60333 | **PRESENTATION:** | Blue coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'C' on the opposite, unscored face packed in blister strips of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | COSMOS Limited | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road, P.O. Box 41433 - 00100, Nairobi, 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 weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 38 Page 3517 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 3.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 38 Page 3517 | No tablet less than 80% [n=6] | Fluconazole 93.5% (RSD=3.9%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 38 Page 3517 | 90.0 - 110.0% | Fluconazole 99.9% (RSD=0.3%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:01-03-2016 |
| REVIEWER: | DR. M. KWENA |  | DATE:09-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-10-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-16-2016 |