**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/600

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | SULFRAN-DS TABLETS | | REF. NO: NDQB201604855 |
| **DATE RECEIVED:** 07.04.2016 | **LABEL CLAIM:** | Each tablet contains: Sulphamethoxazole BP 800 mg and Trimethoprim BP 160 mg. | |
| **BATCH NO.:** 620459 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a blister strip of 10 tablets and 10 such strips packed in a unit box. | |
| **MGF. DATE:** Mar. 2016 | **MANUFACTURER:** | UNIVERSAL Corporation Ltd. | |
| **EXP. DATE:**  Feb. 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** |
| **Identification** |  | USP 38 NF 33 Page 5399 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 5.0 and 9.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5399 | No Tablet Less Than 80% [n=6] | Sulfamethoxazole 100.8% (RSD=0.5%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** |  | USP 38 NF 33 Page 5399 | No Tablet Less Than 80% [n=6] | Trimethoprim 102.2% (RSD=0.2%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5399 | 93.0 - 107.0 % | Sulfamethoxazole 99.5% (RSD=0.3%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 5399 | 93.0 - 107.0 % | Trimethoprim 99.8% (RSD=0.7%, n=9) | **COMPLIES:COMPLIES** |
| **Uniformity of Weight** |  | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from the mean tablet weight | None Deviates | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. S. MWANGI |  | DATE:27-04-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:05-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-10-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |