**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/489

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | SANDROX - 500 CAPSULES | | REF. NO: NDQD201602766 |
| **DATE RECEIVED:** 18.02.2016 | **LABEL CLAIM:** | Each hard gelatin capsule contains; Cefadroxil monohydrate USP equivalent to anhydrous Cefadroxil 500 mg. | |
| **BATCH NO.:** 104415004 | **PRESENTATION:** | Hard gelatin capsules with a red coloured cap and a grey coloured body, filled with a pale yellow powder, packed in a blister strip of 10 capsules in a unit box and 10 such boxes packed in a larger box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | SANCE Laboratories Pvt. Ltd. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | VI/51B, P.B. No. 2, Kozhuvanal, Pala, Kottayam - 686523, Kerala, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Tanzania Food & Drug Authority (TFDA) Mandela Road,-Mabibo-External, P.O BOX 77150, Dar es Saleam, TANZANIA | |
| DS/INS/005 (010/D/I/1516) | **TEST(S) REQUESTED:** | Uniformity of Weight, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 capsules content deviate by more than 7.5% from mean capsule content weight | None Deviates | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2642 | 90.0 - 120.0% | 97.3% (RSD=0.4%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:30-03-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:30-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-31-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-12-2016 |