**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/155

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | CLOFEN(R) 12.5 mg SUPPOSITORIES | | **REF. NO: NDQD201605977** |
| **DATE RECEIVED:** 26-05-2016 | **LABEL CLAIM:** | Each suppository contains: Diclofenac Sodium 12.5 mg. | |
| **BATCH NO.:** 0015 | **PRESENTATION:** | Off white coloured, bullet shaped suppositories packed in plastic strip of 5 suppositories, 2 such strips in a printed box. | |
| **MFG. DATE:** Aug. 2014 | **MANUFACTURER:** | GULF Pharmaceutical Industries. | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | Ras Al Khaimah, U.A.E. | |
| **CLIENT REF NO:** | **CLIENT:** | Goodman Agencies Ltd., P. O. Box 38823 - 00623, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 suppositories deviate by more than 5% from mean suppository weight | None Deviates | **COMPLIES** |
| **Identification** | UV Vis Spectrophotom | Adopted In - house Method | The UV/Vis Spectrum of the assay sample preparation exhibits a maxima at 285 +/- 1 nm | The UV/Vis Spectrum of the assay sample preparation exhibited a maxima at 285 nm. | **COMPLIES** |
| **Assay** | UV Vis Spectrophotom | Adopted In - house Method | 90.0 - 110.0% | 101.2% (RSD=0.4%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 07-12-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 30-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-07-2016 |