**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/2

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | GLUCOFIT-850 TABLET | | REF. NO: NDQD201503120 |
| **DATE RECEIVED:** 2005-03-20 | **LABEL CLAIM:** | Each film coated tablet contains: Metformin Hydrochloride BP 850 mg. | |
| **BATCH NO.:** TT184 | **PRESENTATION:** | white flavored powder for reconstitution in 100ml amber bottle inside a unit box. | |
| **MGF. DATE:** 1970-01-01 | **MANUFACTURER:** | RATNAMANI Healthcare Pvt. Ltd | |
| **EXP. DATE:**  1970-01-01 | **ADDRESS:** | Survey No.: 750/1, Village-Indrad,Ahmedabad-Mehsana Highway, Ta. Kadi,Dist. Mehsana - 382721, Gujarat,INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | GEFLOR HEALTHCARE KENYA LIMITED P.O BOX 6275, 00100- NAIROBI, KENYA | |
| - | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | USP 37 N.F 32 Vol.3 Page 3730 | NMT 2 tablet content deviate by more than 5% from mean tablet content weight | None Deviates | **COMPLIES** |
| **Identification** | UV | USP 37 N.F 32 Vol.3 Page 3730 | UV Absorbance Spectrum of the Assay sample preparation corresponds to that in the assay standard preparation | UV Absorbance Spectra of Sample and Standard preparation are super-imposable. | **COMPLIES** |
| **Dissolution** | hplc | USP 37 N.F 32 Vol.3 Page 3730 | No tablet less than 75% | 100% (RSD = 1.1% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC | USP 37 N.F 32 Vol.3 Page 3730 | 95 - 105% | 100.8% (RSD = 0.9% ; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | CLEMENT MWANGI |  | DATE:03-09-2015 |
| REVIEWER: | DR. ERNEST MBAE |  | DATE:03-18-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:05-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-25-2015 |