**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/508

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LEVOTIL 500 TABLETS | | REF. NO: NDQD201601652 |
| **DATE RECEIVED:** 12.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains; Levofloxacin Hemihydrate USP Eq. to Levofloxacin 500 mg, Excipients q.s. | |
| **BATCH NO.:** T-0006 | **PRESENTATION:** | Brick-red coloured, caplet shaped, biconvex faced tablet, single scored on one face and plain on the other, packed in an aluminium blister strip of 10 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Nov.2015 | **MANUFACTURER:** | CENTURION Laboratories PVT.Ltd. | |
| **EXP. DATE:**  Oct.2018 | **ADDRESS:** | Plot No. P-2, Savali Bio - Tech Park, Tal: Savali, Dist: Vadodara, Gujarat, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | NEXTGEN Parmaceuticals (K) Ltd. P.O Box 20539- 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 tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT; 7.1 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Adopted In-House Method | No tablet less than 85.0% [n=6] | 98.3% (RSD=0.5%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0% | 100.5% (RSD=0.9%; n=6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:30-03-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:30-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-04-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-14-2016 |