**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/524

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | VIDALASTA 20 Tablets | | REF. NO: NDQA201509399 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Tadalafil 20 mg | |
| **BATCH NO.:** 350058 | **PRESENTATION:** | Beige coloured, tear drop shaped, biconvex faced tablets, embossed '20' on one face and 'T' on the other, packed in a blister strip in of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | CENTURION Laboratories (Division of Centurion Remedies Pvt. Ltd.) | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | G/5 & G/6, Industrial Estate Gorwa, Baroda - 390016, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** |  |  |  |  | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 5435 | Acceptance Value (AV) of the 30 dosage units < 15% and no unit less than 76% and no unit greater 127% | AV=28 | **DOES NOT COMPLY** |
| **Identification** | HPLC | USP 38 NF 33 Page 5435 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 12.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5435 | After 10 Mins No tablet less than 40% (n=6): After 30 Mins No tablet less than 80% (n=6) | 68% (RSD=19.7%, n=6)) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5435 | After 10 Mins No tablet less than 40% (n=6): After 30 Mins No tablet less than 80% (n=6) | 93% (RSD=3.2%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5435 | 90.0 - 110.0 % | 104.1% (RSD=1.1%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. S. MWANGI |  | DATE:02-02-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:03-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-19-2016 |