**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/309

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | CHAGUO LANGU TABLETS | | **REF. NO: NDQC2016061132** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains Levonorgestrel BP 0.15 mg and Ethinylestradiol BP 0.03 mg. | |
| **BATCH NO.:** 10560 | **PRESENTATION:** | Off-white coloured, circular shaped, biconvex faced tablets, packed in a blister strip of 21 tablets and 3 such such strips placed in a printed box. | |
| **MFG. DATE:** Sep. 2011 | **MANUFACTURER:** | FAMY Care Ltd. | |
| **EXP. DATE:**  Aug. 2016 | **ADDRESS:** | Plot 20 & 21, Pharmez, NH 8A, Nr. Village Matoda, Ahmedabad 382 213, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LET/05/08.03.2016/0055 | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 4087 | Acceptance value (AV) of 10 dosage units NMT 15% | Levonorgestrel AV=1% (n=10) | **COMPLIES** |
| **Uniformity of Content** |  |  |  | Ethinylestradiol AV=3% (n=10) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4087 | Retention time of the major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 6.3 and 10.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4087 | No tablet less than 65% | Levonorgestrel Average | **COMPLIES** |
| **Dissolution** |  |  |  | 98% (Range |  |
| **Dissolution** |  |  |  | 96 - 100% (RSD= 1.6%; n=6) |  |
| **Assay** | HPLC | Adopted USP 38 NF 33 Page 4087 | 90.0 - 110.0% | Levonorgestrel 98.1% (RSD=0.2%; n=10) | **COMPLIES** |
| **Assay** |  |  |  | Ethinylestradiol 96.1% (RSD=0.2%; n=10) |  |

**CONCLUSION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-19-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |