**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/140

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MICROLUT (R) TABLETS | | **REF. NO: NDQD2016061134** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each contains: Levonorgestrel 0.03 mg. | |
| **BATCH NO.:** 34098B | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 35 tablets, 3 such strips packed in a printed box. | |
| **MFG. DATE:** Oct. 2013 | **MANUFACTURER:** | BAYER Schering Pharma AG. | |
| **EXP. DATE:**  Oct. 2018 | **ADDRESS:** | GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LPOP/06/11.03.2016/0211 | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | BP 2016 Vol. III Page 765 | Acceptance value of the ten (10) dosage units is NMT 15% | AV = 4% (n=10) | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Vol III Page 765 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | BP 2016 Vol III Page 765 | No tablet less than 80% [n=6] | Average = 86% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 83 - 88% (RSD = 2.6%; n = 6) |  |
| **Assay** | HPLC | BP 2016 Vol III Page 765 | 95.0 - 105.0% | 98.7% (RSD = 1.8% ; n = 10) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 08-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-04-2016 |