**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/141

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| **PRODUCT** | MICROLUT® TABLETS | | **REF. NO: NDQD2016061138** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each tablet contains Levonorgestrel 0.03 mg. | |
| **BATCH NO.:** 41148B | **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:** Feb. 2014 | **MANUFACTURER:** | BAYER Pharma AG | |
| **EXP. DATE:**  Feb. 2019 | **ADDRESS:** | 13342 Berlin GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LPOP/02/09.03.2016/0164 | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **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 = 3% (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 85% [n=6] | Average = 85% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 83 - 88% (RSD=2.3, n=6) |  |
| **Assay** | HPLC | BP 2016 Vol. III Page 765 | 95.0 - 105.0% | 96.6% (RSD=0.3%, n=10) | **COMPLIES** |

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

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| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 20-07-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 22-07-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-04-2016 |