**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/145

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| **PRODUCT** | LEVONORGESTREL TABLETS BP | | **REF. NO: NDQD2016061142** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each uncoated tablet contains: Levonorgestrel BP 0.75 mg. | |
| **BATCH NO.:** LG401 | **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 unit box. | |
| **MFG. DATE:** May 2014 | **MANUFACTURER:** | FAMY Care Ltd. | |
| **EXP. DATE:**  Apr. 2019 | **ADDRESS:** | 1608/1609, G.I.D.C., Sarigam - 396155, Valsad, Gujarat, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LECP/08/08/03/2016/0051 | **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 = 6% (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 6.3 -/+ 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 = 87% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 80 - 92% (RSD=5.2; n=6) |  |
| **Assay** | HPLC | BP 2016 Vol III Page 765 | 95.0 - 105.0% | 97.1% (RSD=2.0%; n=10.0) | **COMPLIES** |

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

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| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 27-06-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 22-07-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-04-2016 |