**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/278

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| **PRODUCT** | MICROGYNON (R) ED Fe TABLETS | | **REF. NO: NDQD2016061136** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | 1 beige coloured tablet contains Levonorgestrel 0.15mg and Ethinylestradiol 0.03mg, 1 brown tablet contains Ferrous fumarate 75 mg. | |
| **BATCH NO.:** 390A | **PRESENTATION:** | 21 beige coloured, circular shaped, biconvex faced tablets packed along with 7 brown coloured circular shaped, biconvex faced tablets in a blister strip and 3 such strips in a printed box. | |
| **MFG. DATE:** May 2012 | **MANUFACTURER:** | BAYER Schering Pharma AG. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LETF/05/09.03.2016/0093 | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 4087 | Acceptance Value (AV) of 10 dosage units is NMT 15% | Levonorgestrel AV=5% (n=10) Average | **COMPLIES** |
| **Uniformity of Content** |  |  |  | 106.0% (RSD=0.2%; n=10) | **COMPLIES** |
| **Uniformity of Content** |  |  |  | Ethinylestradiol AV=3% (n=10) Average |  |
| **Uniformity of Content** |  |  |  | 96.2% (RSD=0.3%; n=10) |  |
| **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 6.0 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** |  |  |  | 97% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 96 - 99% (RSD=1.3%; n=6) |  |
| **Assay** | HPLC | Adopted USP 38 NF 33 Page 4087 | 90.0 - 110.0% | Levonorgestrel 106.0% (RSD=0.2%; n=10) | **0** |
| **Assay** |  |  |  | Ethinylestradiol 96.2% (RSD=0.3%; n=10) |  |

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

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| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-23-2016 |