**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/219

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| **PRODUCT** | ENSKYCE(TM) TABLETS | | **REF. NO: NDQD201512639** |
| **DATE RECEIVED:** 17-12-2016 | **LABEL CLAIM:** | Each light orange film -coated tablets contains: desogetrel 0.15 mg and ethiylestradiol USP 0.03 mg, Each green tablet contains inert ingredients | |
| **BATCH NO.:** L-500369 | **PRESENTATION:** | 21 light orange coloured, circular shaped, biconvex faced tablets embossed 'L 21' on one face and 'LU' on the other and 7 green coloured, circular shaped, biconvex faced tablets embossed 'L 22' on one face and 'LU' on the other copacked in a wallet and 3 such wallets in a printed box. | |
| **MFG. DATE:** Not Indicated | **MANUFACTURER:** | LUPIN Limited | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | Pithampur (M.P.) - 454775, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Nairobi Enterprise Ltd, P. O. Box 43472 - 00100, Nairobi, KENYA. | |
|  | **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 439 and Page 547 | Each individual content is between 85 and 115% of the average content | Desogestrel Range 97 - 103% (n=10) | **COMPLIES** |
| **Uniformity of Content** |  |  |  | Ethinyl estradiol Range 96 - 103% (n=10) |  |
| **Identification** |  | BP 2016 Vol. III page 439 and Page 547 | RT of the component peaks in the assay sample preparations correspond to those in the assay standard preparations. | Super-imposable peaks at RT; 5.7 and 9.8 -/+ 10% min. present in the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | BP 2016 Vol. III Page 439 | No tablet less than 80% | Desogestrel 90.2% (RSD = 6.7%; n = 6) | **COMPLIES** |
| **Dissolution** | HPLC |  |  |  |  |
| **Assay** |  | BP 2016 Vol. III Page 439 | 90.0 - 105.0% | Desogestrel 95.5% (RSD = 1.4%; n = 10) | **COMPLIES** |
| **Assay** | HPLC | BP 2016 Vol. III Page 547 | 90.0 - 110.0% | Ethinyl estradiol 93.8% (RSD = 2.3%; n = 10) |  |

**CONCLUSION:** The sample complies with the specifications for the tests performed. It was however noted that the date of manufacture was not indicated.

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| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 08-09-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 08-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-02-2016 |