**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/81

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| **PRODUCT** | I-PILL TABLETS 1.5 mg | | **REF. NO: NDQD201605905** |
| **DATE RECEIVED:** 05-05-2016 | **LABEL CLAIM:** | Each uncoated tablet contains Levornogestrel Ph. Eur 1.5 mg. | |
| **BATCH NO.:** GH51665 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel edged tablets, plain on both faces, packed in a blister strip of 1 tablet in a unit box, 10 such boxes packed in a bigger box | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | Verna Indl. Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, 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 765 | Acceptance value of the ten (10) dosage units is NMT 15% | 7% (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 9.3 -/+ 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 = 94% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 95% (RSD=0.8%, n=6) |  |
| **Assay** | HPLC | BP 2016 Vol III Page 765 | 95.0 - 105.0% | 93.5% (RSD=1.0%, n=10.0) | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed. However, it was noted that the outer box only has the Batch number, manufacturer and expiry date printed on it, no manufacturer.

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 06-03-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 08-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |