**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/507

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| **PRODUCT** | LEVOFLOX 250 TABLETS | | REF. NO: NDQD201511536 |
| **DATE RECEIVED:** 05.11.2015 | **LABEL CLAIM:** | Each film - coated tablet contains: Levofloxacin Hemihydrate equivalent to Levofloxacin 250 mg. | |
| **BATCH NO.:** GC50899 | **PRESENTATION:** | Pink coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in an aluminium blister strip of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Apr.2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Mar.2017 | **ADDRESS:** | Verna Indl. Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C. | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT; 8.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In-House Method | No tablet less than 85.0% [n=6] | 104.2% (RSD=0.9%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 - 105.0% | 102.2% (RSD=1.3%; n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:11-23-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:02-17-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-04-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-14-2016 |