**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/132

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| **PRODUCT** | LUFI - 500 TABLETS | | **REF. NO: NDQC2016061114** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each film - coated tablet contains: Levofloxacin Hemihydrate equivalent to Levofloxacin 500 mg. | |
| **BATCH NO.:** BUY245006 | **PRESENTATION:** | Cream coloured, caplet shaped, biconvex faced tablets, single scored on both faces, packed in a blister strip of 10 tablets in a printed box. | |
| **MFG. DATE:** Oct. 2015 | **MANUFACTURER:** | IPCA Laboratories Ltd. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | Plot No.255/1, Athal, Silvassa 396 230 (D & NH), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LVF/07/08/03/2016/0143 | **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 | One Deviates (+6%) | **COMPLIES** |
| **Identification** | HPLC | Adopted In - house Method | RT of the Major Peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 5.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Adopted In - house Method | No tablet less than 85% (n = 6) | Average = 99% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 98 - 101%, (RSD=1.0%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 95.0 - 105.0 % | 101.6% (RSD=0.7%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 06-24-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 07-04-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-30-2016 |