**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | GFLOX INFUSION 200 mg /100 mL | | REF. NO: NDQD201504182 |
| **DATE RECEIVED:** 16.04.2015 | **LABEL CLAIM:** | Each 100 mL contains Gatifloxacin 200 mg, Glucose Anhydrous B.P. 5% w/v & Water for injection B.P. q.s. | |
| **BATCH NO.:** 443909 | **PRESENTATION:** | Clear, light straw coloured solution for intravenous infusion, contained in a clear colourless 100 mL plastic infusion bottle fitted with a white flip off cap in a unit box. | |
| **MGF. DATE:** May 2014 | **MANUFACTURER:** | ABACUS Parenteral Drugs Ltd. | |
| **EXP. DATE:** May 2016 | **ADDRESS:** | Block 191, Plot No. 114, Kinga, Mukono, Kampala, UGANDA. | |
| **CLIENT REF NO:** | **CLIENT:** | ABACUS Pharma (A) Ltd. Abacus Complex, Off Baba Dogo Road Ruaraka, P.O Box 66829 -00800, Nairobi, KENYA | |
| - | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2012 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Identification** |  |  |  |  | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Manufacturer' In - House Method | NMT 1.5 EU/mL | 1.1 X 10-7 EU/mL | **COMPLIES** |
| **Assay** | UV/Polarimetry | Manufacturer' In - House Method | 90.0 - 110.0% | Gatifloxacin 92.0%, (RSD=0.1%, n=9) Glucose Anhydrous 98.6% (RSD = 0.1%, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer' In - House Method | 4.0 - 5.5 | 4.5 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:22-12-2015 |
| ANALYST: | MR. M. SANGALE |  | DATE:22-12-2015 |
| ANALYST: | DR. M. KWENA |  | DATE:22-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-15-2016 |