**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | APIDRAÂ® INJECTION | | REF. NO: NDQD201509292 |
| **DATE RECEIVED:** 24.09.2015 | **LABEL CLAIM:** | Each mL contains 100 Units insulin glulisine (equivalent to 3.49 mg). Also contains; Also contains; metacresol, sodium chloride trometamol, Polysarbate 20 , concentrated hydrochloric acid, sodium hydroxide , water for injection . | |
| **BATCH NO.:** 3F133A | **PRESENTATION:** | Clear colourless solution for subcutaneous injection, contained in a 3 mL clear colourless glass cartridge, Packed on a blister rack carrying five (5) ampoules in a unit box. | |
| **MGF. DATE:** Dec. 2013 | **MANUFACTURER:** | SANOFI-Aventis Deutscland GmbH. | |
| **EXP. DATE:** Dec. 2015 | **ADDRESS:** | D-65926 Frankurt am Main, GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | SANOFI AVENTIS PO BOX 20337 NAIROBI | |
|  | **TEST(S) REQUESTED:** | Bacterial Endotoxin | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Bacterial Endotoxin** | LAL | Adopted from USP 38 NF 33 Vol. 2 Page 3871 | NMT 80 EU/100 IU | 4.0 x 10-4 EU/100 IU | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:15-01-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:15-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-21-2016 |