**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/667

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| **PRODUCT** | ENDULIN VIAL (TM) INJECTION | | REF. NO: NDQD201509278 |
| **DATE RECEIVED:** 10.09.2015 | **LABEL CLAIM:** | Each mL contains Insulin Glargine (r-DNA Origin) 100 IU, m-Cresol 2.7 mg/mL (as preservative), excipients q.s. | |
| **BATCH NO.:** BF15002438 | **PRESENTATION:** | Clear colourless solution for subcutaneous injection, packed in a clear colourless 3 mL glass vial fitted with an aluminium band and a purple coloured flip-off cap in unit box. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | BIOCON Limited. | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | Plot No. 2-4, Phase IV, Bommasandra-Jigani Link Road, Bommasandra post, Bangalore - 560 099, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Surgilinks Limited P.O. Box 14461 - 00800, Nairobi,KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** |  |  |  |  | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | Microbial growth | **DOES NOT COMPLY** |
| **Identification** | HPLC | USP 38 NF 33 page 3876 | RT of the major peak in assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 19.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 page 3876 | Not more than 80 EU/100 IU | 1.6\*10-3 EU/100 IU | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 3876 | 95.0 - 105.0 IU/mL | 99.1 IU/mL (RSD = 0.5% ; n = 9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 page 3876 | 3.5 - 4.5 | 4.0 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:15-09-2015 |
| ANALYST: | DR. L.KARANJA |  | DATE:11-03-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:18-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-04-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-30-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |