**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/824

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| **PRODUCT** | ARLIN IV INFUSION | | **REF. NO: NDQD201511566** |
| **DATE RECEIVED:** 19.11.2015 | **LABEL CLAIM:** | Each ml contains: Linezolid INN 2 mg. | |
| **BATCH NO.:** 215010 | **PRESENTATION:** | Clear, colourless solution for intravenous infusion, contained in a 300 mL clear colourless glass infusion bottle fitted with a grey rubber closurer. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | BEXIMCO Pharmaceuticals Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Tongi, BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | Madawa Pharmaceuticals Ltd. P.O Box 29787-00202, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | Adopted 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 12 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 -110.0 | 98.0% (RSD=0.3%; n=6) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-House Method | 4.6 - 5.0 | 4.9 | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V Appendix XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Adopted In-House Method | NMT 1.75 EU/mg | 5.5 X 10-6 EU/mg | **COMPLIES** |

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

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 24-05-2016 |
| **ANALYST:** | DR . E. MUTUA | .......................................................... | DATE: 24-05-2016 |
| **ANALYST:** | DR. G. WANG’ANG’A | .......................................................... | DATE: 24-05-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |