**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/259

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| **PRODUCT** | LINEZOLID 600 mg TABLETS | | **REF. NO: NDQD2016061237** |
| **DATE RECEIVED:** 30.06.2016 | **LABEL CLAIM:** | Each film-coated tablet contains Linezolid 600 mg. | |
| **BATCH NO.:** ID61288 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face and embossed 'CL' on the other, 20 tablets packed in a white plastic multidose container in a printed box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Dec. 2016 | **ADDRESS:** | Plot 9 & 10 Indores SEZ Pithampur, M.P. 454 775, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharma Specialities Ltd. P. O. Box 49146 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | Weight | Manufacturer's In-House Method | Acceptance value of ten dosage dosage units is NMT 15% | AV=2% (n=10) | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's 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 4.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 85% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 93% Range |  |
| **Dissolution** |  |  |  | 91 - 93% (RSD=0.9%; n=6) |  |
| **Dissolution** |  |  |  |  |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 - 105.0% | 99.6% (RSD=1.3%; n=9), | **COMPLIES** |
| **Assay** |  |  |  |  |  |
| **Assay** |  |  |  |  |  |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 08-09-2016 |
| **ANALYST** | DR. M. KWENA | .......................................................... | DATE: 08-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-17-2016 |