**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/503

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| **PRODUCT** | GAMOK(R) 1.2 g INJECTION | | REF. NO: NDQD201512630 |
| **DATE RECEIVED:** 10.12.2015 | **LABEL CLAIM:** | Each vial contains sodium Amoxicillin equivalent to 1000 mg amoxicillin and Potassium clavulanate equivalent to 200 mg of Clavulanic Acid | |
| **BATCH NO.:** 20150601 | **PRESENTATION:** | Off white coloured, free flowing power for injection, packed in a clear colourless glass vial fitted with a green plastic flip off cap and 10 such vials in a unit box. | |
| **MGF. DATE:** Jun. 2015 | **MANUFACTURER:** | SINOPHARM Weiqida Pharmaceutical Co.,Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Economic & Technological Development Zone, Datong, Shanxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 vials deviate by more than 10% from mean vial weight | Two deviate (-16, +16) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT; 3.8 & 6.0-/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Adopted In-House Method | NMT 0.25 EU/mg | 8.8 x 10-5 EU/mg | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 107.5% | Amoxicillin; 99.0% (RSD = 1.7%; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 107.5% | Clavulanic Acid; 102.7% (RSD = 0.8%; n = 9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-House Method | 8.0 - 10.0 | 9.0 | **COMPLIES** |

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

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|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-13-2016 |