**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/543

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| **PRODUCT** | BENZYLPENICILLIN SODIUM INJECTION | | **REF. NO: NDQA201509298** |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each vial contains: Benzylpenicillin (As Sodium) BP 1,000,000 I.U. (600mg). | |
| **BATCH NO.:** 143012083 | **PRESENTATION:** | White free flowing powder for intramuscular or intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure and an aluminum band and 50 such vials packed in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | REYOUNG Pharmaceutical Co. Ltd. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | No.6, Erlangshan Road, Yiyuan County, Shandong Province, P.R. CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| BNZP/07/12.03.2015/00220 | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII G. | < 2 vial contents deviate by more than 10% from mean vial content weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4785 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4797 | 90.0 - 120.0% | 109.3% (RSD = 1.9% ; n = 7) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A. | No Microbial Growth | No Microbial Growth | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 17-11-2015 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 03-03-25016 |
| **REVIEWER:** | DR. E TANUI | .......................................................... | DATE: 21-03-2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 04-18-2016 |