**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/540

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | BENZYLPENICILLIN G SODIUM INJECTION BP 5 MEGA | | **REF. NO: NDQA201509295** |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each vial contains: Benzyl Penicillin Sodium B.P. 5,000,000 I.U (3 g). | |
| **BATCH NO.:** 588130203 | **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:** Feb. 2013 | **MANUFACTURER:** | CSPC Zhongnuo Pharmaceuticals (Shijiazhuang) Co., Ltd. | |
| **EXP. DATE:**  Feb. 2016 | **ADDRESS:** | No. 47 Fengshou Road, Shijiazhung, Hebei Province, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| BNZP/07/13.03.2015/00303 | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A. | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4797 | 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% | 114.0% (RSD = 1.2% ; n = 7) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **A** |  | .......................................................... | DATE: |