**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/482

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| **PRODUCT** | MEDIPEN INJECTION | | REF. NO: NDQD201511570 |
| **DATE RECEIVED:** 19.11.2015 | **LABEL CLAIM:** | Each vial contains Benzylpenicillin Sodium BP equivalent to Benzylpenicillin 1,000,000 i.u. | |
| **BATCH NO.:** 586150133 | **PRESENTATION:** | Off white free flowing powder for intramuscular or intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure and an aluminium band and 50 such vials in a unit box. | |
| **MGF. DATE:** Jan. 2015 | **MANUFACTURER:** | CSPC Zhongnuo Pharmaceuticals (Shijiazhuang) Co. Ltd. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | No. 47 Fengshou Road, Shijiazhuang City, Hebei Province, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique P.O. Box 10397 - 00400, Nairobi, Kenya | |
|  | **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 | None Deviates | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 vol V App XVI A | No microbial growth | No Microbial Growth | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 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** |
| **Bacterial Endotoxin** | HPLC | USP 38 NF 33 4797 | Less than 0.01 EU/100 IU | 3.5\*Ã¢â‚¬â€10-6 EU/100 IU | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 4797 | 90.0 - 120.0% | 105.1% (RSD = 1.8% ; n = 7) | **COMPLIES** |
| **Acidity/Alkalinity** | HPLC | USP 38 NF 33 4797 | 5.0 - 7.5 | 6.7 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:15-12-2015 |
| ANALYST: | DR. L. WANGARI |  | DATE:03-03-2016 |
| ANALYST: | DR. G. WAN'GANG'A |  | DATE:18-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-04-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-11-2016 |