**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/746

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| **PRODUCT** | ZOMETA R 4 mg/5 mL INJECTION | | REF. NO: NDQD201510449 |
| **DATE RECEIVED:** 22.10.2015 | **LABEL CLAIM:** | Each 5 ml vial contains: Zoledronic Acid 4 mg | |
| **BATCH NO.:** S0374 | **PRESENTATION:** | Clear colourless concentrate for solution for infusion, contained in a 5 mL clear plastic vial fitted with a grey rubber closure, an aluminum band and a red flip off cap, packed in a folding box. | |
| **MGF. DATE:** Nov. 2014 | **MANUFACTURER:** | Novartis Pharma Stein AG | |
| **EXP. DATE:**  Oct. 2017 | **ADDRESS:** | Stein, SWITZERLAND. | |
| **CLIENT REF NO:** | **CLIENT:** | Norvatis Pharma services Inc P.O Box 46057-00100,Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | Uniformity of Volume, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | Adopted 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 2.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90.0 - 110.0 % | 102.0% (RSD=0.6% ; n=9) | **COMPLIES** |
| **Acidity/Alkalinity** |  | Adopted In-House Method | 5.7 - 6.7 | 6.3 | **COMPLIES** |
| **Uniformity of Volume** |  | Manufacturer's In-House Method | 5.0 - 5.6 mL | 5.2 mL | **COMPLIES** |
| **Sterility** |  | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** |  | Manufacturer's In-House Method | NMT 13.6 EU/mL | 2.3 x 10-5 EU/mL | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:09-12-2015 |
| ANALYST: | DR. S. MWANGI |  | DATE:27-05-2016 |
| REVIEWER: | DR. N. MWAURA |  | DATE:09-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-14-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-27-2016 |