**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** 0

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | STERILE QUININE DIHYDROCHLORIDE CONCENTRATE BP 300 mg/mL, 2 mL AMPOULE INJECTION | | REF. NO: NDQA201511469 |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each mL contains Quinine Dihydrochloride BP 300 mg. Water for Injection BP q.s. | |
| **BATCH NO.:** SF405X | **PRESENTATION:** | Clear colourless solution contained in a 2 mL colourless glass ampoule, packed on a plastic blister pack of 10 ampoules a unit box. | |
| **MGF. DATE:** Apr.2014 | **MANUFACTURER:** | GLAND Pharma Limited. | |
| **EXP. DATE:**  Mar.2017 | **ADDRESS:** | D.P. Pally, Hyderabadad-500 043, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Acidity/Alkalinity** |  | BP 2016 Vol.111 Page 1072 | 1.5 - 3.0 | 1.6 | **COMPLIES** |
| **Identification** |  | BP 2016 Vol.111 Page 1072 | A;The addition of Sulphuric acid to the solution produced a Blue Fluorescence B; Addition of few drops of HCL the fluorescence disappeared | Blue fluorescence produced Fluorescence dissappeared | **COMPLIES** |
| **Sterility** |  | BP 2016 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 Chapter 85 | NMT 350 EU/vial | 1.54 x 10-02 EU/vial | **COMPLIES** |
| **Assay** |  | BP 2016 Vol.111 Page 1072-3 | 95.0 - 105.0% | 99.7% (RSD=0.4%;n=3) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. E. NGAMAU |  | DATE:14-06-2016 |
| ANALYST: | MR. M. SANGALE |  | DATE:14-06-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:14-06-2016 |