**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

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| --- | --- | --- | --- |
| **PRODUCT** | Sterile Quinine Dihydrochloride Concentrate BP | | **REF. NO: NDQA201508083** |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each ml contains Quinine Dihydrochloride BP 300 mg | |
| **BATCH NO.:** SF410X | **PRESENTATION:** | Straw coloured solution for intramuscular/slow intravenous use, contained in a 2 mL amber-coloured glass ampoule, packed in a plastic rack of 10 ampoules in a unit box. | |
| **MGF. DATE:** Jul.2014 | **MANUFACTURER:** | GLAND pharma Limited. | |
| **EXP. DATE:** Jun.2017 | **ADDRESS:** | D.P.Pally Hyderabad-500 043, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Assay** | Titration | B.P. 2012 Vol 3 Page 3252 | 95.0%-105.0% | 97.1% (n=3; RSD= 1.0%) | **COMPLIES** |
| **Identification** | Colour | Ph. Int. 5th Edition On line version | Strong blue fluorescence is produced | Strong blue fluorescence produced | **COMPLIES** |
| **Sterility** | Membrane Filtration | B. P. 2013 Vol. V App. XVIA | No Microbial Growth | No Microbial Growth | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications of the tests perfomed.

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 08-12-2015 |
| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 09-30-2015 |
| **REVIEWER:** | DR. N. MWAURA | .......................................................... | DATE: 10-14-2015 |
| **ANALYST:** | SERAH MUTERU | .......................................................... | DATE: 11-10-2015 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-20-2015 |