**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/333

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | GSUNATE (R) IV/IM INJECTION | | **REF. NO: NDQD201609113** |
| **DATE RECEIVED:** 2016-09-22 | **LABEL CLAIM:** | Each vial contains: Artesunate 60 mg. The combi pack contains 1 mL ampoule of Sodium Bicarbonate Injection BP 5.0 % w/v and 5 mL ampoule of Sodium Chloride Injection BP 0.9 % w/v. | |
| **BATCH NO.:** Powder: BI15008P Diluent 1: B020 Diluent 2: B016 | **PRESENTATION:** | Off white crystalline powder for injection in a clear glass vial with a navy blue coloured flip-off cap contained in a plastic blister pack supplied together one clear glass ampoule of 1 mL sodium bicarbonate and one clear glass ampoule of 5 mL sodium chloride in a unit box. | |
| **MFG. DATE:** Powder: May 2015 Diluent 1:Apr. 2015 Diluent 2: Mar. 2015 | **MANUFACTURER:** | BLISS Indasi Lifescience Pvt. Ltd. | |
| **EXP. DATE:**  Powder: Apr. 2017 Diluent 1: Mar. 2020 Diluent 2: Feb. 2020 | **ADDRESS:** | Plot No.73 to 76, Silver Industrial Estate, Bhimpore, Daman - 396210 (UT), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pan Pharmaceuticals Ltd., P. O. Box 47393 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 vials deviate by more than 10% from mean weight | None Deviates | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | Bacterial Endotoxin | Manufacturer's Method | Powder (Artesunate); NMT 5.8 EU/mg, Diluent 1 (NaCl); NMT 0.5 EU/mL Diluent 2 (NaHCO3); NMT 5 EU/mEq | Powder; 4.2x10-6 EU/mg, Diluent 1; 3.7x10-8 EU/mL, Diluent 2; 2.9x10-5 EU/mEq | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's Method | 3.5 - 4.5 | 4.0 | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's Method | 90.0 - 110.0% | Artesunate 100.2% (RSD=1.1%; n=9) | **COMPLIES** |
| **Assay** | Titration |  |  | Sodium Bicarbonate 99.6% (RSD=0.4%; n=3) | **COMPLIES** |
| **Assay** |  |  |  | Sodium Chloride 107.0% (RSD=0.04%; n=3) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DUNCAN OLUOCH | .......................................................... | DATE: 09-23-2016 |
| **ANALYST:** | ERIC NGAMAU | .......................................................... | DATE: 09-23-2016 |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 11-11-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |