**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | D50 GLUCOSE INTRAVENOUS INFUSION | | REF. NO: NDQD201509274 |
| **DATE RECEIVED:** 10.09.2015 | **LABEL CLAIM:** | Each 100 mL contains: Glucose Anhydrous B.P 50.0 g & Water for injection B.P q.s. | |
| **BATCH NO.:** 423904 | **PRESENTATION:** | Clear, colourless solution for intravenous infusion, contained in a transparent plastic 100 mL infusion bottle fitted with a white flip off cap in a unit box. | |
| **MGF. DATE:** May.2014 | **MANUFACTURER:** | ABACUS Parenteral Drugs Ltd. | |
| **EXP. DATE:** May.2016 | **ADDRESS:** | Block 191, plot No.114, Kinga, Mukono, P.O Box 31376, Kampala, UGANDA. | |
| **CLIENT REF NO:** | **CLIENT:** | ABACUS Pharma (A) Ltd. Abacus Complex, Off Baba Dogo Road Ruaraka, P.O Box 66829 -00800, Nairobi, KENYA | |
| pv 160 | **TEST(S) REQUESTED:** | Sterility, Related Substances, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. IV App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Related Substances** | UV | BP 2016, Vol 3 Page. 635 | UV Absorbance of the test solution at 284 nm is NMT 0.25 | The absorbance of test solution at 284 nm was Less than 0.25 | **COMPLIES** |
| **Identification** |  | Test not done, please confirm and remove if true | Test not done, please confirm and remove if true | Test not done, please confirm and remove if true | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 Vol 2 page 3065 | Less than 10 EU/g | Less than 5.8 \* 10-4 EU/g (Include the symbol) | **COMPLIES** |
| **Assay** | POLARIMETRY | BP 2016, Vol 3 Page. 635 | 95.0%-105.0% | Glucose anhydrous (Average=98.6%, RSD=-, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Vol 2 page 3065 | 3.2 - 6.5 | 3.3 | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:07-12-2015 |
| ANALYST: | MR. E. NGAMAU |  | DATE:05-10-2015 |
| ANALYST: | MR. D. MOENGA. |  | DATE:10-11-2015 |
| REVIEWER: | DR. E. TANUI |  | DATE:12-10-2015 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:07-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-15-2016 |