**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/151

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| **PRODUCT** | ZODOX-50 SOLUTION FOR INFUSION | | **REF. NO: NDQD2016061176** |
| **DATE RECEIVED:** 2016-06-14 | **LABEL CLAIM:** | Each 1 mL contains 2 mg Doxorubicin Hydrochloride. | |
| **BATCH NO.:** T00613 | **PRESENTATION:** | Brick red coloured solution for intravenous and intravesical administration, contained in a 25 mL vial with a pink flip-off cap and grey plastic base in a printed box. | |
| **MFG. DATE:** Dec. 2015 | **MANUFACTURER:** | INTAS Pharmaceuticals Limited. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | Matoda 382 210 Dist. Ahmedabad, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ACCORD HEALTHCARE LIMITED TEL:+91-79-66117451/66094251 | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP Vol. V 2016 App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | Kinetic ChomoLAL | USP 38 NF 33 page 3215 | NMT 2.2 USP EU/mg | 2.0x10-7 EU/mg | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 3215 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 2.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 page 3215 | 2.5 - 4.5 | 3.0 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 3215 | 90.0 -115.0 % | 98.4% (RSD=0.4%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 07-12-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 30-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-07-2016 |