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Vetindia Pharmaceuticals Limited
A-6/1, Electronic Complex, Kushaiguda, Hyderabad-62

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
WORKING STANDARD ANALYSIS REPORT

Mfg.lic.No:52/HD/AP/95/F/R 21 JUN 2016

| | | |
|---|-----------------------------|--------------------|
| Name of the Material: OXYTETRACYCLINE HYDROCHLORIDE | Material Code: 095 | W.S.No: VWS/095/15 |
| Batch No: Working Standard | Mfg.Date: 09/2014 | Exp.Date: 09/2017 |
| Name of the Manufacturer: Hebei Shengxue Dacheng Pharmaceuticals Co Ltd | | |
| Condition: Good | Quantity Received: 50 g | |
| Date of Analysis: 08/12/2015 | Date of Report: 09/12/2015 | |
| Inward No: 014 | A.R.NO: VWSR/014/15 | |
| Ref \$TP No: VIPL/QC/RM/095/A | Ref SOP No: VIPL/QC/GEN/017 | |

| S.NO | TEST | SPECIFICATION | RESULT |
|------|--------------------------------|---|----------------------------------|
| 1. | Appearance | Yellow, crystalline powder, hygroscopic. | Yellow crystalline powder |
| 2. | Solubility | Freely soluble in water, sparingly soluble in ethanol (96%). Solutions in water become turbid on standing, owing to the precipitation of oxytetracycline. | Complies |
| 3. | Identification | A. Thin layer Chromatography B. A deep red colour develops. Add the solution to 2.5ml of water. The colour becomes yellow C. It gives reaction of chlorides | Complies Complies Complies |
| 4. | pH | 2.3 to 2.9 | 2.58 |
| 5. | Specific optical rotation | -188 to -200 | -193.89 |
| 6. | Specific absorbance | Maximum at 353nm(270 to 290) | 286.95 |
| 7. | Light-absorbing impurities | At about 430nm, Not more than 0.50 At about 490nm, Not more than 0.20 | 0.174 0.018 |
| 8. | Heavy metals | Maximum 50 ppm | < 50ppm |
| 9. | Water | Maximum 2.0% | 1.41% |
| 10. | Sulphated ash | Maximum 0.5% | 0.12% |
| 11. | Bacterial endotoxins | Less than 0.4 IU/mg | < 0.4 IU/mg |
| 12. | Assay (anhydrous substance) | 95.0% to 102.0% | 98.60% |

REMARKS: THE MATERIAL COMPLIES WITH BP2011 SPECIFICATIONS IN THE ABOVE RESPECTS.

ANALYSED BY
 Prasad 09/12/2015

CHECKED BY
 K. Latha
 09/12/2015



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