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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

Name of the Material: OXYTETRACYCLINE DIHYDRATE	Material Code: 096	W.S.No: VWS/096/15
Batch No: Working Standard	Mfg.Date: 09/2015	Exp.Date: 09/2020
Name of the Manufacturer: Century Pharmaceuticals Ltd		
Condition: Good	Quantity Received: 50 g	
Date of Analysis:30/12/2015	Date of Report: 30/12/2015	
Inward No:063	A.R.NO: VWSR/063/15	
Ref STP No: VIPL/QC/RM/096/A	Ref SOP No: VIPL/QC/GEN/017	

S.NO	TEST	SPECIFICATION	RESULT
1.	Appearance	Yellow, crystalline powder.	Yellow ,crystalline powder
2.	Solubility	Very slightly soluble in water. It dissolves in dilute acid and alkaline solutions.	Complies
3.	Identification	A. Thin-layer chromatography B. The colour becomes yellow C. Any opalescence in the solution is not more intense than that in a mixture of 1 ml of dilute nitric acid, 5ml of a 0.021g/l solution of potassium chloride and 1 ml of silver nitrate solution.	Complies The colour became to yellow
4.	pH	4.5 to 7.5	5.10
5.	Specific optical rotation	-203° to -216°	-208.47°
6.	Specific absorbance	290 to 310 determined at 353 nm(anhydroussubstance)	306.34
7.	Light - absorbing impurities	The absorbance determined at 430 nm has a maximum of 0.25(anhydrous substance) The absorbance determined at 490 nm has a maximum of 0.20(anhydrous substance)	0.138 0.013
8.	Related substances	Should comply as per BP	Complies
9.	Heavy metals	Maximum 50 ppm	< 50 ppm
10.	Water	6.0% to 9.0%	8.60 %
11.	Sulphated ash	Maximum 0.5%	0.02 %
12.	Assay (anhydrous substance)	95.0% to 102.0%	98.1%
13.	Bacterial Endotoxins	NMT 0.4 EU/mg	< 0.4EU/mg

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

K. Latha
ANALYSED BY
Latha
30/12/2015

6/12/2015
CHECKED BY
Prasad



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