SANCE LABORATORIES PRIVATE LIMITED,KOZHUVANAL

QUALITY CONTROL: DEPARTMENT

CERTIFICATE OF ANALYSIS

C21-1

Date : 30/04/14

A. R. No. : RM04121129
Name Of the Sample : Cefotaxime Sodium IP/USP
Code : AM011-5
Unit : Kgs
Manufacturer : Zhuhai United Laboratories Co. Ltd.
Supplier : Zhuhai United Laboratories Co. Ltd

Spec. : IP/USP
Ref No. : RM/D/5/AM011/R0
Total Qty. : 140.000
Batch No. : 304112050
Mfg. Date : Dec- 13
Exp Date : Nov- 17

Sr. No.	TEST	RESULT	LIMIT
1	Description	Conforms:Off-white crystalline hygroscopic powder.	Off-white to pale yellow crystalline hygroscopic powder.
2	Clarity & Colour of solution	Complies	Shall meets the requirements
3	Chromatographic Purity	Individual impurity 0.675%. Total impurity 0.693%	Any individual impurity - NMT 1.0% Sum of all impurities - NMT 3.0%
4	Specific Optical Rotation	+59.89	When determined in a 1%w/v solution, shall be between +58 and +64
5	Absorbance Of 10%w/v Solution	Complies (0.122)	NMT 0.2 at 430nm
6	Solubility	Conforms:Freely soluble in water practically insoluble in organic solvents.	Freely soluble in water practically insoluble in organic solvents.
7	Identification C	Conforms:Gives the reaction of sodium salts.	Gives the reaction of sodium salts.
8	pH	5.32	Between 4.5 and 6.5
9	Loss On Drying	0.69%	NMT 3.0 % w/w
10	Bacterial Endotoxins	Less than 0.20 EU / mg	NMT 0.20 EU / mg
11	Sterility Test	Passes as per party COA	Should be sterile
12	Assay	962.8 mcg/mg	920 to 964 mcg/mg of cefotaxime.
13	Identification A & B	A)Retention time are identical.B)Complies.	A) The chromatogram of the assay obtained as directed in the assay exhibits a major peak for cefotaxime, the retention time of which corresponds to that excibited in the cromatogram of the standard preparation obtained as directed inthe Assay B)The IR spectra as