WRS ... C3-6



Steril-Gene

Department: Quality control

Format No.: QC/101/F/10-00 SOP No.: QC/101

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TITLE: Certificate Of Analysis For In-House Reference Standard / Working standard

Certificate Of Analysis For In-House Reference Standard / Working standard

Standard Name	:	Cefuroxime Axetil USP			
Lot No.	:	NAP	Mfg./batch No.	ı	CAAN140566
Standard No	:	WS/018/15-01	Initiation date of Analysis	:	02/07/15
Date of Mfg.	;	11/2014	Valid upto	:	02/07/16
Date of Exp.	1	.10/2017	Pharmacopeia Reference	:	USP
Manufacturer Name	:	Janani Pharmaceutical Pvt Ltd	Storage condition	:	2 to 8°C

S. No.	Test	Specification Limit	Results	
01	Description	White to almost white amorphous powder	Almost white amorphous powder	
02	Identification by IR	The infrared spectrum concordant with Cefuroxime Axetil RS	Complies	
03	Water	NMT 1.5 %	0.70 %	
04	Assay (on anhydrous basis)	745µg/mg to 875µg/mg	826 μg/mg	
05	Assay (As such basis)	NAP	820 μg/mg	

Remarks: The Above standard is certified/ not certified for use as working standard. The above standard evaluated with reference standard of USP CRS Lot No: R011M0

	PREPARED BY	REVIEWED BY	APPROVED BY	
	(Executive QC)	(Asst.Manager QC)	(Head QC)	
Signature	PL	8	ATRIL GENE	
Date :	21/20/20	03/07/15	0 300	