


C66-3

 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		



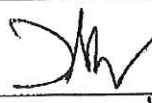
Certificate Of Analysis For In-House Reference Standard / Working standard

Standard Name	:	CEFUROXIME AXETIL- USP			
Lot No.	:	NAP	Mfg./batch No.	:	CAAN160159
Standard No	:	WS/023/16-01	Initiation date of Analysis	:	15/06/16
Date of Mfg.	:	03/2016	Valid upto	:	14/06/17
Date of Exp.	:	02/2019	Pharmacopeia Reference	:	USP
Manufacturer Name	:	Covalent Lab	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 IR spectrum of the sample spectrum should be concordant with Cefuroxime axetil RS spectrum	Complies
03	Water By KF	Not more than 1.5%	0.74%
04	Assay(On Anhydrous basis)	NLT 745µg/mg and NMT 875µg/mg	832µg/mg
05	Assay(As such basis)By HPLC	NAP	826µg/mg

Remarks: The Above standard is certified/ not certified for use as a Working Standard.

The above working standard evaluated with Cefuroxime Axetil -USP RS Lot No: R011M0.

	PREPARED BY (Executive QC)	REVIEWED BY (Asst. Manager QC)	APPROVED BY (Head QC)
Signature			
Date :	18/06/16	18/06/16	18/06/16

