C66 C66-3 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 Anhydrousbasis)**	NLT745µg/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

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