



ISO 9001:2015 CERTIFIED CERTIFICATE OF ANALYSIS

Product Name	Cilastatin EP impurity-E	
Molecular Formula	C ₁₀ H ₁₇ NO ₅ S (Free Base) C ₁₀ H ₁₈ ClNO ₅ S (Salt)	
Molecular Weight	263.31 (Free base) 299.77 (HCl salt)	
Batch Number	XX-XXXX	
Batch Quantity	XXX	
Date of Manufacturing	DD-MM-YYYY	
Date of Analysis	DD-MM-YYYY	
Next Retest Date	DD-MM-YYYY	
Catalogue Number	DCTI-C-000462	
CAS Number	DCTI-C-000980	
COA Number	PA-XXXX	
IUPAC Name	(R)-7-((2-amino-2-carboxyethyl)thio)-2-oxoheptanoic acid hydrogen chloride	
Storage and Handling	2-8°C	

Sl. No	* Test	Result
	Description	
1.	Identification i) By IR ii) By NMR iii) By MS	--
2.	Chromatographic Purity (% by HPLC)	--

Remarks: *Test or tests as mentioned above may vary as per the product nature or customer's requirement

Function	Compiled by	Reviewed by	Reviewed by	Approved by
Name	xxx	xxx	xxx	xxx
Department	Pharma Standards QC	Pharma Standards QC	Quality Assurance	Quality Assurance
Sign and Date				

Attachments	IR, NMR, MS spectra, HPLC Chromatogram.
Date of Shipment	DD-MMM-YYYY

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