

CERTIFICATE OF ANALYSIS

Product Name:	Cefotaxime Sodium
CAS Number:	64485-93-4
Batch Number:	24/MFM/3136
Manufacturing Date:	May 2024
Expiry Date:	May 2027
Storage Conditions:	2 - 8°C
Specification:	US Pharmacopeia

TESTS	SPECS	RESULTS
Appearance:	Crystalline Powder	Crystalline Powder
Colour:	White to off-white	Complies
Solubility:	Clear, colourless solution	Complies
Assay (HPLC, on dried basis)	916 – 964 µg/mg	956 µg/mg
Specific optional rotation	+58 to +64°	+61°
Loss on drying:	Max 3%	2.4%
pH:	4.5 – 6.5	5.4
Chromatographic purity		
- Any individual impurity	<= 1.0%	0.4%
- Sum of all impurities	<= 3.0%	1.5%
Bacterial endotoxins	< 0.050 EU/mg	Complies
Visible particles	Meets the requirements	Complies
Residual solvents	Meets the requirements	Complies

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11th November 2024