

Gojira Fine Chemicals, LLC

Quality Products & Services Meeting Customer Needs
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Date: February 15, 2018

Specification

Cefotaxime Sodium Salt USP

Catalog Number:CS1003CAS Number:64485-93-4Molecular Formula: $C_{16}H_{16}N_5NaO_7S_2$

Molecular Weight: 477.45Storage: $2^{\circ}\text{C} - 8^{\circ}\text{C}$

Retest Period: Four years from date of manufacture.

Test	Specification
Appearance	White to almost-white crystalline powder
Assay (Anhydrous Basis)	916 – 964 μg/mg
Identification	To meet requirements
Specific Rotation	+58° to +64°
pH	4.5 – 6.5
Clarity and Color of Solution	Clear
	A(430nm) ≤2.0
Chromatographic Purity	
1.Any individual impurity	≤ 1.0%
2.Sum of all impurities	≤ 3.0%
Moisture (LOD)	≤ 3.0%
Bacterial Endotoxins	≤ 0.20 EU/mg
Visible Particles	To meet requirements
Particulate Matter	
≥ 10 um	≤ 6000/g
≥ 25 um	≤ 600/g
This product meets the specifications for USP32.	

Approved: John Grubb

John Grubb, PhD Gojira Fine Chemicals

Quality Manager

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