



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Cefazolin Sodium Sterile

Batch No.: HDC20230508

Manufacturing Date: May 8th, 2023

Report Date: May 9th, 2023

Packing: 5kg/tin; 2 tins/carton

Batch Quantity: 309.60kg

Retest Date: Apr 1st, 2025

Standard: USP43

Test Items	Specifications	Test Results
Appearance	White to off-white, practically odourless, crystalline powder, or white to off-white solid	Conforms
Specific Optical Rotation	-10°~ -24°	-18°
Identification	A. Infrared Absorption	Conforms
	B. The retention time of the major peak for cefazolin in the sample solution corresponds to that of the standard solution, as obtained in the assay.	Conforms
	C. It responds to the tests for sodium	Conforms
pH Value	4.0 ~ 6.0	5.5
Related Compounds	(1) Tetrazolylacetic acid: ≤1.0%	Not detected
	(2) Tetrazolylacetamide acetal: ≤1.0%	0.3%
	(3) Cefazolin open-ring lactone or cefazolin 3-hydroxymethyl: ≤0.5%	0.02%
	(4) Methylthiadiazole thiol: ≤1.0%	0.3%
	(5) 7-Aminocephalosporanic acid: ≤1.0%	Not detected
	(6) Cefazolin 3-methyl analog: ≤1.0%	0.1%
	(7) Cefazolin lactone: ≤1.0%	0.1%
	(8) Cefazolin acetoxy analog: ≤1.0%	0.02%
	(9) Cefazolin deacylated: ≤1.0%	Not detected
	(10) Cefazoloic acid isomers: ≤1.0%	0.1%
	(11) Cefazolin epimer: ≤1.0%	0.01%



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	(12) Cefazolin pivaloyl: $\leq 1.0\%$	0.2%
	(13) Any individual unspecified impurity: $\leq 0.1\%$	0.04%
	(14) Total impurities: $\leq 3.5\%$	1.0%
Water	Not more than 6.0%	0.7%
Bacterial endotoxins	Not more than 0.15EU/mg	Conforms
Sterility	Should be sterile	Conforms
Assay	NLT 89.1% and NMT 110.1% of Cefazolin Sodium, calculated on the anhydrous basis	95.3%

Conclusion: The testing results of this batch are complied with the USP43 Specifications.

Storage Conditions: Preserved in tight, light-resistant containers; kept at room temperature away from heat and moisture.