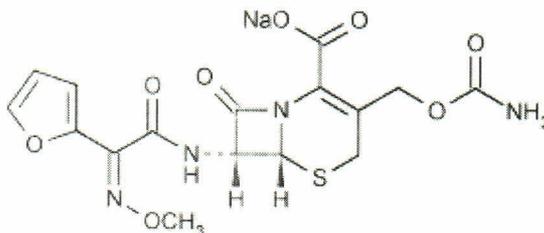




Batch no 251107-69
 Mf date Nov 10 2025
 Exp date Nov 09 2028
 Batch size 284.57 kg

Molecular Structure



Molecular Formula $C_{16}H_{15}N_4NaO_8S$
 Molecular Weight 446.37
 CAS Registry Number 56238-63-2

Jan 13 2026

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White or faintly yellow powder	Conforms
Identification	HPLC, sodium tests	Positive
Solubility	Freely soluble in water, soluble in methanol, very slightly soluble in alcohol, in ether, in ethyl acetate, and in chloroform	Conforms
pH	6.0 ~ 8.5	6.9
Water	≤ 3.5%	2.2%
Particulate matter	≥ 10 μm ≤ 6000	Conforms
	≥ 25 μm ≤ 600	Conforms
Related substances	Impurity A ≤ 1.0%	0.03%
	Any unspecified impurity ≤ 1.0%	0.05%
	Total impurities ≤ 3.0%	0.26%
Residual solvents	Acetone ≤ 5000 ppm	60 ppm
	Ethanol ≤ 5000 ppm	100 ppm
Bacterial endotoxins	≤ 0.10 EU/mg of Cefuroxime	Conforms
Assay (HPLC) oab	855 ~ 1000 μg/mg of $C_{16}H_{15}N_4O_8S$	960 μg/mg

Packaging & storage	Preserve in tight, light-resistant containers
Conclusion	Material complies with current USP-NF2024