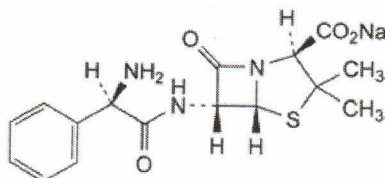


Batch no 1052503013  
Mf date Mar 21 2025  
Expiry Mar 20 2028

Molecular Structure



Molecular Formula  $C_{16}H_{18}N_3NaO_4S$

Molecular Weight 371.4

CAS Registry Number 69-52-3

Jul 22 2025

Tests	Specifications	Results
Appearance	White or almost white powder, hygroscopic	White powder hygroscopic
Identification	IR, sodium test	Positive
Clarity of solution	Not more opalescent than reference solution II	< 1
Absorbance of solution	At 430nm $\leq 0.15$	0.01
pH	8.0 ~ 10.0	9.2
Specific optical rotation	+258 ~ +287°	+278°
Related substances	Any other impurity $\leq 2\%$	0.35%
	Ampicillin dimmer $\leq 4.5\%$	1.9%
N,N-Dimethylaniline	$\leq 0.002\%$	ND
2-Ethylhexanoic acid	$\leq 0.8\%$	ND
Methylene chloride	$\leq 0.2\%$	0.02%
Toluene (In-house)	$\leq 0.089\%$	ND
MIBK (In-house)	$\leq 0.45\%$	ND
Isopropanol (In-house)	$\leq 0.5\%$	ND
Ethyl acetate (In-house)	$\leq 0.5\%$	ND
Acetone (In-house)	$\leq 0.5\%$	ND
N-Butanol (In-house)	$\leq 0.5\%$	ND
Water	$\leq 2.0\%$	0.62%
Visible particles	Meets the requirements	Conforms
Sub-visible particles	$\leq 2250$ particles/g ( $\geq 10$ um) $\leq 225$ particles/g ( $\geq 25$ um)	378 particles/g 24 particles/g
Assay (oab)	91.0 ~ 102.0%	95.3%

Packaging and Storage	Preserve in tight containers
Conclusion	Material complies with EP10.0