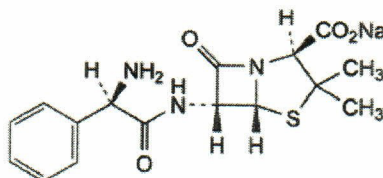


Batch no 1052603025  
 Mf date Mar 28 2026  
 Expiry Mar 27 2029

Molecular Structure



Molecular Formula  $C_{16}H_{18}N_3NaO_4S$   
 Molecular Weight 371.4  
 CAS Registry Number 69-52-3

Apr 13 2026

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
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	9.3
Specific optical rotation	+258 ~ +287°	+276°
Related substances	Any other impurity $\leq 2\%$ Ampicillin dimer $\leq 4.5\%$	0.36% 2.1%
N,N-Dimethylaniline	$\leq 0.002\%$	ND
2-Ethylhexanoic acid	$\leq 0.8\%$	ND
Methylene chloride	$\leq 0.2\%$	0.03%
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	$\leq 2.0\%$	0.6%
Visible particles	Meets the requirements	Conforms
Sub-visible particles	$\leq 2250$ particles/g ( $\geq 10$ $\mu$ m) $\leq 225$ particles/g ( $\geq 25$ $\mu$ m)	380 particles/g 25 particles/g
Assay (oab)	91.0 ~ 102.0%	95.1%

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