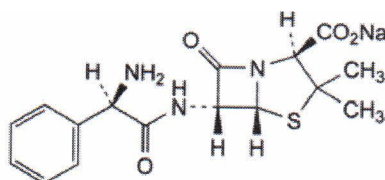


Batch no 1052310010
Mf date Oct 12 2023
Expiry Oct 11 2026

Molecular Structure



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

Jan 09 2024

<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 ≤ 0.15	0.01
pH	8.0 ~ 10.0	9.1
Specific optical rotation	+258 ~ +287°	+279°
Related substances	Any other impurity $\leq 2\%$ Ampicillin dimer $\leq 4.5\%$	0.35% 1.9%
N,N-Dimethylaniline	$\leq 0.002\%$	ND
2-Ethylhexanoic acid	$\leq 0.8\%$	ND
Methylene chloride	$\leq 0.2\%$	0.01%
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	≤ 2250 particles/g (≥ 10 μ m) ≤ 225 particles/g (≥ 25 μ m)	378 particles/g 24 particles/g
Assay (oab)	91.0 ~ 102.0%	95.2%

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

