



Specification

Formula Hill: C₁₆H₁₈N₃NaO₄S
Molar Mass: 371,29 g/mol
CAS N°: 69-52-3

Print Date: 20 October 2020

101090 Ampicillin sodium salt Ph. Eur.

	Specifications
Assay (dried subs)	91,0 - 102,0 %
Identity	
- Identity A	conforms
- Identity B	conforms
- Identity C	conforms
- Identity D	conforms
Appearance	
- White or almost white	conforms
- Hygroscopic powder	conforms
Appearance of solution	conforms
pH	8,0 - 10,0
Solubility	conforms
Specific rotation	258 - 287 °
2-Ethylhexanoic acid	≤ 0,8 %
Methylene chloride	≤ 0,2 %
N,N-Dimethylaniline	≤ 0,0020 %
Related substances	
- Ampicillin dimer	≤ 4,5 %
- Any other impurity (each)	≤ 2 %
Residual Solvents	conforms
Water by KF	≤ 2,0 %

The product cannot be considered as an Active Pharmaceutical Ingredient (API) for human or veterinary use

Conforms to: Ph. Eur. specification