

Cefalexin Monohydrate USP44

Batch no 12052311093 Mf date Nov 13 2023 Exp date Nov 12 2026 Batch size 737.64 kg

Molecular Structure

 $\label{eq:molecular_formula} \mbox{Molecular Formula} \quad \mbox{C_{16}H}_{17}\mbox{$N_3$0}_4\mbox{S.} \mbox{$H_2$0}$

Molecular Weight

365.40

CAS Registry Number

23325-78-2

Nov 29 2023

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Tests	<u>Specifications</u>		Results
Appearance	White or almost white crystalline powder		Conforms
Identification	IR, UV		Positive
Specific rotation	+149 ~ +158°		+153°
Crystallinity	Meets the requirements		Conforms
Solubility	Meets the requirements		Conforms
рН	3.0 ~ 5.5		4. 9
Water	4.0 ~ 8.0%		5.5%
Related substances	7-ADCA	≤ 1.0%	0.06%
	α-phenylglycine	≤ 1.0%	0.06%
	Any other impurity	≤ 1.0%	0. 06%
	Total impurities	≤ 5.0%	0. 18%
Residual solvents	Acetone	≤ 0.5%	0. 07%
	Dichloromethane	≤ 0.06%	0. 0005%
	Methanol	≤ 0.3%	0. 02%
Residue on ignition	≤ 0.2%		0. 08%
Assay (odb)	950 ~ 1030 ug/mg		1002 ug/mg
2			1002 ug/mg
Packaging & storage	Preserve in tightly	closed containers, stora	age in a
	cool and dry place.		
Conclusion	Material complies with USP44		
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