



Zhejiang Anglikang Pharmaceutical Co., Ltd.

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METAPHARMACEUTICAL
INDUSTRIAL SLU

2ATJCCS01LA000007-01
Version 02

Zhejiang Anglikang Pharmaceutical Co., Ltd.
No.1000 Shengzhou North Road, Shengzhou City, Shaoxing Zhejiang, China 312400

Certificate of Analysis

Product Name:	Cefalexin Monohydrate (Compacted)		
Batch No.:	12052504164	Package Size:	25kg/drum
Specification:	EP11.0	Batch Size:	735.79kg
Mfg. Date:	22 April 2025	LAB Record No.:	BPAC31-2504064
Report Date:	09 July 2025	Exp. Date:	March 2028
ITEMS	SPECIFICATIONS		RESULTS
Appearance	White or almost white, crystalline powder.		Almost white, crystalline powder
Identification	The IR spectrum conforms to that of reference standard.		Complies
Tests			
pH	4.0~5.5		4.9
Specific optical rotation	+149°~+158°		+153°
Related substances	7-ADCA NMT 1.0%		N.D.
	Any other impurity NMT 1.0%		0.08%
	Total impurities NMT 3.0%		0.11%
Methanol	NMT 0.3%		0.005%
Acetone	NMT 0.3%		0.05%
Methylene chloride	NMT 0.06%		0.0004%
N,N-Dimethylformamide	NMT 0.088%		N.D.
Water Content	4.0~8.0%		4.5%
Sulfated ash	NMT 0.2%		0.05%
Assay	95.0 per cent to 102.0 per cent (anhydrous substance)		99.0%
Bulk Density	For Information only		0.56g/ml
Tapped Density	For Information only		0.89g/ml
Remarks:	N,N-Dimethylaniline in this process is not utilized		
Conclusion:	The product complies with specification EP11.0.		

Reporter:

王意 2025.07.09

Reviewer:

张明群
2025.07.09