



SYNERGY

JIANGXI SYNERGY PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

CAS: 169590-42-5

Version: 05

No.:M2205028

Product name		Celecoxib	
According to		USP43	Batch No. 111-20220419M
Package		Fibre drum	Manufacturing date 2022.04.15
Package size		15KGS/drum	Report date 2022.04.28
Quantity		557.1KGS	Retest date 2026.04.14
Items		Specification	Results
Appearance		A white or almost white crystalline powder	White crystalline powder
Solubility		Freely soluble in anhydrous ethanol; soluble in methylene chloride; practically insoluble in water	Conform
Identification	A	IR: Complies with spectrum of CRS	Conform
	B	HPLC: In assay test, the main peak retention time of sample solution should comply with that of reference solution	Conform
Water		Not more than 0.5%	0.1%
Residue on ignition		Not more than 0.2%	0.0%
Related substance	Impurity A: not more than 0.4%		<0.03%
	Impurity B: not more than 0.10%		<0.03%
	Max individual impurity: not more than 0.10%		<0.03%
	Total impurity: not more than 0.5%		<0.03%
Residual solvent	Ethanol: not more than 5000ppm		40ppm
	Toluene: not more than 890ppm		1ppm
Assay(anhydrous basis)		98.0%-102.0%	99.4%
Conclusion: Complies with USP43			
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Lister: QC Supervisor: QA Supervisor: 

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