



東岳藥業
DONGYUE PHARMA

启东东岳药业有限公司
Qidong Dongyue Pharmaceutical Co., Ltd.

26/11/2025

Certificate of Analysis

Product Name:	Dipyridamole	
Chemical Name:	2,2',2'',2'''-[[4,8-Di(piperidin-1-yl)pyrimido[5,4- <i>d</i>]pyrimidine-2,6-diyl]dinitrilo]-tetraethanol	
CAS No.:	58-32-2	
Molecular Formula:	C ₂₄ H ₄₀ N ₈ O ₄	
Molecular Weight:	504.6	
Batch No.:	SD-202510201	
Quantity:	506.70kg	
Production Date:	October 07, 2025	
Analysis Date:	October 17, 2025	
Retest Date:	October 06, 2027	
Packaging Size:	25kg/fiber drum	
Packaging and Storage:	Protected from light	
Method of Analysis:	EP 11.0	
TEST ITEMS	SPECIFICATION	TEST RESULTS
CHARACTER		
Appearance	Bright yellow, crystalline powder	Complies
Solubility	Practically insoluble in water, freely soluble in acetone, soluble in anhydrous ethanol. Freely soluble in diluted hydrochloride acid	Complies
IDENTIFICATION		
IR	Conform to the requirements	Complies
ASSAY		
Assay	98.5%~101.5% on the dried basis	100.4%
IMPURITIES		
Sulfated ash	NMT 0.1%	0.05%
Related substances	Impurity A: NMT 0.5%	0.03%
	Impurity B: NMT 0.5%	0.01%
	Impurity C: NMT 0.5%	Not Detected
	Impurity D: NMT 0.2%	0.02%
	Impurity E: NMT 0.2%	Not Detected
Residual solvents	Any other impurity: NMT 0.10%	0.05%
	Total impurities: NMT 1.0%	0.05%
	Methanol: NMT 0.2%	Not Detected
Benzenesulfonate esters	Ethanol: NMT 0.2%	0.02%
	Sum of methyl p-toluenesulfonate and ethyl p-toluenesulfonate: NMT 3.75ppm	Not Detected
SPECIFIC TESTS		
Chlorides	NMT 200ppm	Complies
Loss on drying	NMT 0.5%	0.1%
Conclusion: All of the results conform to EP 11.0 specs.		

Inspector: 刘雪松 2025.11.02

Corrector: 顾天天 2025.11.02

Approver: 朱丹 2025.11.02

质量部