

TR-2002-0023-13

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東岳藥業
DONGYUE PHARMA

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

25/11/2025

Certificate of Analysis

Product Name:	Dipyridamole	
Chemical Name:	2,2',2'',2'''-[[4,8-Di(piperidin-1-yl)pyrimido[5,4-d]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-202510207	
Quantity:	321.00kg	
Production Date:	October 13, 2025	
Analysis Date:	October 19, 2025	
Retest Date:	October 12, 2027	
Packaging Size:	25kg/fiber drum	
Packaging and Storage:	Protected from light	
Method of Analysis:	EP 11.0	
TEST ITEMS CHARACTER	SPECIFICATION	TEST RESULTS
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%	0.04%
Related substances	Impurity A: NMT 0.5%	0.06%
	Impurity B: NMT 0.5%	Not Detected
	Impurity C: NMT 0.5%	Not Detected
	Impurity D: NMT 0.2%	<0.05%
	Impurity E: NMT 0.2%	Not Detected
	Any other impurity: NMT 0.10%	0.10%
	Total impurities: NMT 1.0%	0.2%
Residual solvents	Methanol: NMT 0.2%	Not Detected
	Ethanol: NMT 0.2%	0.01%
Benzenesulfonate esters	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 EP11.0 specs.		

Inspector: 2025.10.30 Corrector: 2025.10.30 Approver: 2025.10.30

质量部