

Dipyridamole EP11.0

Batch no 202405205 Mf date May 14 2024 Retest May 13 2027 Batch size 502.3 kg

Molecular Structure

Molecular Formula $C_{24}H_{40}N_8O_4$ Molecular Weight 504.63 CAS Registry Number 58-32-2

Aug 23 2024

<u>Tests</u>	<u>Specifications</u>	Results
Appearance	Bright yellow crystalline powder	Conforms
Solubility	Practically insoluble in water, freely soluble in acetone, soluble in anhydrous ethanol. Freely soluble in diluted hydrochloride acid	Conforms
Identification	IR	Positive
Sulfated ash	≤ 0.1%	0. 05%
Related substances	Impurity A ≤ 0.5%	< 0.05%
	Impurity B ≤ 0.5%	< 0.05%
	Impurity C ≤ 0.5%	ND
	Impurity D ≤ 0.2%	< 0.05%
	Impurity E ≤ 0.2%	ND
	Any other impurity ≤ 0.1%	< 0.05%
	Total impurities ≤ 1.0%	ND
Residual solvents	Methanol $\leq 0.2\%$	ND
	Ethanol ≤ 0.2%	0. 03%
Benzenesulfonate esters	Sum of methyl p-toluenesulfonate &	ND
	ethyl p-toluenesulfonate ≤ 3.75 ppm	
Chlorides	≤ 200 ppm	Conforms
Loss on drying	≤ 0.5%	0. 05%
Assay (odb)	98. 5 $^{\sim}$ 101. 5% of $C_{24}H_{40}N_8O_4$	99.6%
Packaging & storage	Protected from light	
Conclusion	Material complies with EP11.0	

