

Certificate of Analysis

Product name: **Dipyridamolum**

Batch number / Weight: **22E23-B05-234813 / 25 G**

Producer / Producer Batch Number: S.I.M.S. S.r.l. - Filarone / 199379

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **22E23-B05 / INS-22-5537**

Reference Code / No.: **V02073 / 199379**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Bright yellow, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,5$	0,11	%	
Impurity B	$\leq 0,5$	0,00	%	
Impurity C	$\leq 0,5$	0,00	%	
Impurity D	$\leq 0,2$	$< 0,05$	%	
Impurity E	$\leq 0,2$	$< 0,05$	%	
Any other impurity	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 1,0$	0,11	%	
Chlorides	≤ 200	< 200	ppm	
Loss on drying	$\leq 0,5$	0,04	%	
Sulphated ash	$\leq 0,1$	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dipyridamol	98,5 - 101,5	99,81	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Dominika Soltysik
Qualified Person

22-02-2024

Expiration: 31-12-2026

Conclusion: APPROVED

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