

## Certificate of Analysis

**Product name:** **Dipyridamolum**  
**Batch number / Weight:** **22E23-B05-229244 / 30 G**  
**Analysed according to:** **Ph.Eur.11.1**  
**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	$\leq 200$	$< 200$	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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Fagron Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.  
 ul. Pasternik 26, 31-354 Kraków, Poland  
 tel.: +48 12 3343 512  
 e-mail: biuro@fagron.pl

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

27-06-2023

Expiration: 31-12-2026

Conclusion: APPROVED

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl