

DIPIRIDAMOL (EUR. PH.)			
PRODUCT CODE: 0519		CAS Nº: 58-32-2	ANALYSIS Nº: 385/25
MANUFACTURER BATCH:	SD-202510207	CERTIFICATE ID:	49.403
SUPPLIER BATCH:	----	MANUFACTURING DATE:	13/10/2025
METAPH BATCH:	0391125	RETEST DATE:	19/10/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Bright yellow, crystalline powder	Bright yellow, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, soluble in anhydrous ethanol. It dissolves in dilute mineral acids	Complies (*)
Identification	Complies	Complies
Related substances		
Impurity A	=< 0.5 %	0.05 %
Impurity B	=< 0.5 %	< 0.05 %
Impurity C	=< 0.5 %	Not Detected
Impurity D	=< 0.2 %	< 0.05 %
Impurity E	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.1 %	< 0.05 %
Total impurities	=< 1.0 %	0.05 %
Chlorides	=< 200 ppm	< 200 ppm
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	98.5 - 101.5 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Dipyridamole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Release date: 01/12/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40001590
QIDONG DONGYUE PHARMACEUTICAL CO.,LTD.
No.268 Shanghai Rd., Binjiang Fine Chemical Industry Zone, 268
QIDONG
JIANGSU(China)

Original certificate available upon request

Page 1 of 2

A073_ENG_03

DIPIRIDAMOL (EUR. PH.)			
PRODUCT CODE: 0519		CAS Nº: 58-32-2	ANALYSIS Nº: 385/25
MANUFACTURER BATCH:	SD-202510207	CERTIFICATE ID:	49.403
SUPPLIER BATCH:	----	MANUFACTURING DATE:	13/10/2025
METAPH BATCH:	0391125	RETEST DATE:	19/10/2027

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

Release date: 01/12/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40001590
QIDONG DONGYUE PHARMACEUTICAL CO.,LTD.
No.268 Shanghai Rd., Binjiang Fine Chemical Industry Zone, 268
QIDONG
JIANGSU(China)

Original certificate available upon request

Page 2 of 2

A073_ENG_03