

DILTIAZEM HCL (EUR. PH.)

PRODUCT CODE: 0510	CAS Nº: 33286-22-5	ANALYSIS Nº: 004/23
MANUFACTURER BATCH: 202201104111	CERTIFICATE ID: 36.903	
SUPPLIER BATCH: 0111922	MANUFACTURING DATE: 10/01/2022	
METAPH BATCH: 0031222	EXPIRY DATE: 09/01/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol	Complies
Identification A	Complies	Complies (*)
Identification D	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
pH	4.3 - 5.3	4.8
Specific optical rotation	+115 / +120	+118
Related substances		
Impurity F	=< 0.3 %	0.10 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	0.10 %
Loss on drying	=< 0.5 %	0.12 % (*)
Sulfated ash	=< 0.1 %	0.04 % (*)
Assay	98.5 - 101.0 %	100.6 % (*)
Residual solvents		(**)
Methylene chloride	=< 50 ppm	< 4.9 ppm
Ethanol	=< 3000 ppm	1074 ppm
Toluene	=< 200 ppm	115 ppm
Particle size		
< 150 µm	=< 90 %	98 %
< 50 µm	=< 50 %	75 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed inside the EU.

Diltiazem Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(*) Data controlled by Metapharmaceutical Industrial SL-

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

Analysis date: 12/01/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000885

F.I.S. FABBRICA ITALIANA SINTETICI S.p.A.

Viale Milano, 26

36075 Montebelluna Maggiore

Vicenza (Italia)





DILTIAZEM HCL (EUR. PH.)

PRODUCT CODE: 0510		CAS Nº: 33286-22-5		ANALYSIS Nº: 004/23	
MANUFACTURER BATCH: 202201104111		CERTIFICATE ID: 36.903			
SUPPLIER BATCH: 0111922		MANUFACTURING DATE: 10/01/2022			
METAPH BATCH: 0031222		EXPIRY DATE: 09/01/2027			

STORAGE

Store the container in a fresh, dry and well-ventilated place.

Analysis date: 12/01/2023
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000885
F.I.S. FABBRICA ITALIANA SINTETICI S.p.A.
Viale Milano, 26
36075 Montecchio Maggiore
Vicenza(Itàlia)