



DILTIAZEM HCL (EUR. PH.)					
PRODUCT CODE: 0510	CAS Nº: 33286-2	2-5 ANALY	'SIS Nº: 004/23		
MANUFACTURER BATCH:	202201104111	CERTIFICATE ID:	36.903		
SUPPLIER BATCH:	0111922	MANUFACTURING DATE:	10/01/2022		
МЕТАРН ВАТСН:	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	Complies	
	methylene chloride, slightly soluble in anhydrous		
	ethanol		
Identification A	Complies	Complies (*)	
Identification D	Complies	Complies (*)	
Appearance of solution	Clear and colourless	Complies	
рН	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			

COMPLIES WITH

## REMARKS

Product fully analyzed inside the EU.

European Pharmacopoeia 11.0

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 Montecchio Maggiore

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Vicenza(Itàlia)

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DILTIAZEM HCL (EUR. PH.)					
PRODUCT CODE: 0510	CAS Nº: 33286-22-5		YSIS Nº: 004/23		
MANUFACTURER BATCH:	202201104111	CERTIFICATE ID:	36.903		
SUPPLIER BATCH:	0111922	MANUFACTURING DATE:	10/01/2022		
МЕТАРН ВАТСН:	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

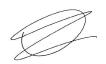
Original certificate available upon request

Manufacturer: 40000885

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