



DILTIAZEM HCL (EUR. PH.)					
PRODUCT CODE: 0510	CAS Nº: 33286-2	2-5 ANAL	NALYSIS Nº: 303/21		
MANUFACTURER BATCH:	202007034127	CERTIFICATE ID:	33.367		
SUPPLIER BATCH:	0098968	MANUFACTURING DATE:	02/07/2020		
МЕТАРН ВАТСН:	0061220	EXPIRY DATE:	01/07/2025		

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		
Tile difference A	ethanol	C (*)	
Identification A	Complies	Complies (*)	
Identification D	Complies	Complies (*)	
Appearance of solution	Clear and colourless	Complies	
рН	4.3 - 5.3	5.1	
Specific optical rotation	+115 / +120	+116.0	
Related substances			
Impurity F	=< 0.3 %	< 0.05 %	
Unspecified impurities	=< 0.10 %	< 0.05 %	
Total impurities	=< 0.3 %	< 0.05 %	
Loss on drying	=< 0.5 %	0.14 % (*)	
Sulfated ash	=< 0.1 %	0.06 % (*)	
Assay	98.5 - 101.0 %	99.7 % (*)	
Residual solvents		(**)	
Methylene chloride	=< 50 ppm	< 4.9 ppm	
Ethanol	=< 3000 ppm	1248 ppm	
Toluene	=< 200 ppm	83 ppm	
Particle size			
< 150 μm	=< 90 %	93 %	
< 50 μm	=< 50 %	56 %	
COMPLIES WITH			

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European Pharmacopoeia 10.0

REMARKS

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.

STORAGE

Analysis date: 05/01/2022

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)

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

Analysis date: 05/01/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

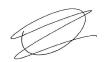
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