



DILTIAZEM HCL (EUR. PH.)

PRODUCT CODE: 0510	CAS Nº: 33286-22-5	ANALYSIS Nº: 303/21
MANUFACTURER BATCH: 202007034127	CERTIFICATE ID: 33.367	
SUPPLIER BATCH: 0098968	MANUFACTURING DATE: 02/07/2020	
METAPH BATCH: 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 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	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

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 Montebelluna Maggiore
 Vicenza (Italia)





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

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