



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230255

Product:	DILTIAZEM HYDROCHLORIDE
Lot:	230255
Expiry date:	17/09/2025
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₂₂ H ₂₆ N ₂ O ₄ S·HCl
Molecular weight:	451,0 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
Melting point	213 °C	Approx. 213° (dec)	
Appearance of solution	Conform	Test PhEur	
pH	4,9	4,3 - 5,3	
Specific rotation	+ 119	(+115)-(+120)	
Related substances (HPLC)	Conform		
Loss on drying	0,13 %	<= 0,5 %	
Elemental impurities	Conform	Test PhEur	#
Sulphated ashes	0,00 %	<= 0,1%	
Assay	99,9 %	98,5 - 101,0 % s.p.s	
Impurity F	0,10 %	<= 0,3 %	
Unspecified Impurities	ND	<= 0,10 %	
Total impurities	0,10 %	<= 0,3 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 23/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00413 FERMION OY

Manufacturer batch: 2019461

Product	Name	Capacity	Batch
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	230255-D-1

1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	230255-D-2
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	230255-D-3
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	230255-D-4
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	230255-D-5
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	230255-J-1
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	230255-J-2
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	230255-J-3
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	230255-J-4
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	230255-J-5
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	230255-G-1
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	230255-G-2
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	230255-G-3
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	230255-G-4
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	230255-O-1
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	230255-O-2
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	230255-O-3
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	230255-E-1
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	230255-E-2
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	230255-E-3
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	230255-E-4

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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