



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 227498

Product:	DILTIAZEM HYDROCHLORIDE
Lot:	227498
Expiry date:	17/09/2025
Reference:	Cumple PhEur10.6
Synonyms:	
Formule:	C ₂₂ H ₂₆ N ₂ O ₄ S·HCl
Poids moléculaire:	451,0 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
Melting point	214 °C	Approx. 213° (dec)	
Appearance of solution	Conform	Test PhEur	
pH	5,2	4,3 - 5,3	
Specific rotation	+118	(+115)-(+120)	
Related substances (HPLC)	Conform		
Loss on drying	0,17 %	<= 0,5 %	
Elemental impurities	Conform	Test PhEur	#
Sulphated ashes	0,00 %	<= 0,1%	
Assay	100,6 % s.p.s	98,5 - 101,0 % s.p.s	
Impurity F	0,08 %	<= 0,3 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	0,08 %	<= 0,3 %	
Residual solvent: Toluene	<= 890ppm	<= 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: 23/02/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00413 FERMION OY

Manufacturer batch: 2019461

Produit	Nom	Capacité	Lot
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	227498-D-1

1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	227498-D-2
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	227498-D-3
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	227498-J-1
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	227498-J-2
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	227498-J-3
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	227498-G-1
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	227498-G-2
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	227498-G-3
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	227498-G-4
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	227498-G-5
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	227498-O-1
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	227498-O-2
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	227498-O-3
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	227498-O-4
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	227498-E-1
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	227498-E-2
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	227498-E-3
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	227498-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

Date d'édition: 21/08/2025