



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241565

Product:	DILTIAZEM HYDROCHLORIDE
Lot:	241565
Expiry date:	30/05/2028
Reference:	Cumple PhEur11.5
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	5,1	4,3 - 5,3	
Specific rotation	+119	(+115)-(+120)	
Related substances (HPLC)	Conform		
Loss on drying	0,12 %	<= 0,5 %	
Elemental impurities	Conform	Test PhEur	#
Sulphated ashes	0,05 %	<= 0,1%	
Assay	98,9 %	98,5 - 101,0 %	
Impurity F	0,17 %	<= 0,3 %	
Unspecified Impurities	0,08 %	<= 0,10 %	
Total impurities	0,25 %	<= 0,3 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Dimethylformamide	< 890 ppm	<= 890 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: 1-Butanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white crystalline powder. Easily soluble in water, methanol, and methylene chloride, slightly soluble in anhydrous ethanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 28/08/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00033 LUSOCHIMICA SPA

Manufacturer batch: DIL 223

Product	Name	Capacity	Batch
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	241565-D-1
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	241565-D-2
1125898	DILTIAZEM CLORHIDRATO Ph.Eur.	1 g	241565-D-3
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	241565-J-1
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	241565-J-2
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	241565-J-3
1125901	DILTIAZEM CLORHIDRATO Ph.Eur.	100 g	241565-J-4
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	241565-G-1
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	241565-G-2
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	241565-G-3
1125902	DILTIAZEM CLORHIDRATO Ph.Eur.	25 g	241565-G-4
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	241565-O-1
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	241565-O-2
1125905	DILTIAZEM CLORHIDRATO Ph.Eur.	500 g	241565-O-3
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	241565-E-1
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	241565-E-2
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	241565-E-3
1400221	DILTIAZEM CLORHIDRATO Ph.Eur.	5 g	241565-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

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