

## Diltiazem HCL

<b>CODE ARTICLE:</b> 97909	<b>BATCH:</b> 0111928	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 09/06/2022	<b>TEST:</b> QC-00243567	
<b>EXPIRY DATE:</b> 09/01/2027	<b>FABRICATION DATE:</b> 10/01/2022	<b>MR:</b> 451,00
<b>CAS:</b> [33286-22-5]	<b>FORMULA:</b> C22H26N2O4S. HCl	
<b>SYNONYMS / BOTANICAL NAME:</b> Clorhidrato de latiazem; Hidrocloruro de diltiazem		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION, CHEMICAL TEST	CONFORM				PH.EUR.
IDENTIFICATION, CHLORIDES REACTION	CONFORM				PH.EUR.*
SPECIFIC ROTATION	118 DEGREES		115	120	PH.EUR.
DISSOLUTION ASPECT	CONFORM -			Límpida e incolora (5% agua)	PH.EUR.
PH (1%)	4,8 -		4,3	5,3	PH.EUR.
<b>RELATED SUBSTANCES</b>					
TOTAL IMPURITIES	0,10 %			<=0,3	PH.EUR.
UNSPECIFIED IMPURITIES	<0,05 %			<=0,10	PH.EUR.
IMPURITY F	0,10 %			<=0,30	PH.EUR.
LOSS ON DRYING	0,03 %			<=0,50	PH.EUR.*
SULPHATED ASHES	0,00 %			<=0,10	PH.EUR.
ASSAY (DRY SUBSTANCE)	100,84 %		98,5	101	PH.EUR.*
TAPPED DENSITY	0,55 G/ML		0,4	0,75	Manufacture's Standard
<b>RESIDUAL SOLVENTS</b>					
METHYLENE CHLORIDE	<4,9 ppm			<=50	Manufacture's Standard
ETHYL ALCOHOL	1074 ppm			<=3000	Manufacture's Standard
TOLUENE	115 ppm			<=200	Manufacture's Standard
<b>PARTICLE SIZE</b>					
PARTICLE SIZE < 150 MICRAS	98 %		>=90		Manufacture's Standard
PARTICLE SIZE < 50 MICRAS	75 %		>=50		Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 10, USP				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				
<i>This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.</i>					

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 47972 F. I. S.P.A. (Italia) Manufacturer Batch: 202201104111 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



**Diltiazem HCL**

<b>CODE ARTICLE:</b> 97909	<b>BATCH:</b> 0111928	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 09/06/2022	<b>TEST:</b> QC-00243567	
<b>EXPIRY DATE:</b> 09/01/2027	<b>FABRICATION DATE:</b> 10/01/2022	<b>MR:</b> 451,00
<b>CAS:</b> [33286-22-5]	<b>FORMULA:</b> C22H26N2O4S. HCl	
<b>SYNONYMS / BOTANICAL NAME:</b> Clorhidrato de latiazem; Hidrocloruro de diltiazem		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
------	---------	-------	-----	-----	--------



**Silvia Sancho-Tello Ripoll**  
Technical Director.

**This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.**

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 47972 F. I. S.P.A. (Italia) Manufacturer Batch: 202201104111 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

