GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Diltiazem HCL

CODE ARTICLE: 91152	**BATCH:** 0125448 **Active pharmaceutical ingredient**
TEST DATE: 15/02/2024	**TEST:** QC-00261413
EXPIRY DATE: 12/11/2028 **FABRICATION DATE:** 14/11/2023	**MR:** 451,00
CAS: [33286-22-5]	**FORMULA:** C22H26N2O4S. HCl
SYNONYMS / BOTANICAL NAME: Clorhidrato de latiazem; Hidrocloruro de diltiazem	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		White or almost white crystal powder.	PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN METHANOL				PH.EUR.*
SOLUBLE	FFREELY SOLUBLE IN METHYLENE CHLORIDE				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN ANHIDROUS ETHANOL				PH.EUR.*
IDENTIFICATION					
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%)	5	-	4,3	5,3	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,1% (PASS)	-		<=0,3% (<=3x Área Ref B)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL (0,05%) (PASS)	-		<=0,10% (<=Área Ref B)	PH.EUR.*
IMPURITY F	0,1% (PASS)	-		<=0,3% (<=3x Área Ref B)	PH.EUR.*
LOSS ON DRYING	0,02	%		<=0,50	PH.EUR.*
SULPHATED ASHES	0,01	%		<=0,10	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,3	%	98,5	101	PH.EUR.*
TAPPED DENSITY	0,63	G/ML	0,4	0,75	Manufacture's Standard
RESIDUAL SOLVENTS					
METHYLENE CHLORIDE	<4,9	ppm		<=50	Manufacture's Standard
ETHYL ALCOHOL	1604	ppm		<=3000	Manufacture's Standard
TOLUENE	110	ppm		<=200	Manufacture's Standard
PARTICLE SIZE					
PARTICLE SIZE < 150 MICRAS	96	%	>=90		Manufacture's Standard
PARTICLE SIZE < 50 MICRAS	66	%	>=50		Manufacture's Standard

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: 202311034084 Manufacturer original CoA available under request

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GOOD MANUFACTURING PRACTICE GMP

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TEST	RESULTS	Units	MIN	MAX	METHOD
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

NON-sterile

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

Silvia Sancho-Tello Ripoll
Technical Director.

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