

Company managed and coordinated by the sole shareholder, Holding F.I.S. - S.p.A.

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Share Capital E 10.000.000 i.v.
R.I. - C.F. & VAT NR. IT01712670247
MV1002266
R.E.A. Vicenza 179183
www.flavi.com

CERTIFICATE OF ANALYSIS

Material	7130000 DILTIAZEM HYDROCHLORIDE ✓	Batch	16A42A1820 ✓
Manuf.Date	11 Apr 2016	Retest Date	10 Apr 2021 ✓
Inspection Lot	040000152710	Purchase order	19405
Ship-to party	10079739	Delivery	3031700098
Name	GUINAMA S.L.		
Address	C/ PRAGA s/n POL. IND. GUTENBERG 46185	Certificate Model ID	CE7130000 T1-3

Characteristic	Specification	Results
According to USP		
APPEARANCE	White crystalline powder	Compliant
IDENTIFICATION		
- IR Spectrum	Conforms to ref. STD	Compliant
- HPLC Retention Time Value	Conforms to ref. STD	Compliant
- Chemical Test	Positive	Compliant
SPECIFIC OPTICAL ROTATION (25°C)	110,0 - 116,0 Degree	112,9
LOSS ON DRYING	<= 0,50 % w/w	0,21
RESIDUE ON IGNITION	<= 0,10 % w/w	0,02
HEAVY METALS (Limit Test)	Not more than 20ppm	Compliant
RELATED COMPOUNDS (HPLC)		
- Desacetyl Diltiazem	Max 0,50 % w/w	0,02
- Max. Imp. other than Desacetyl DTZ	Max 0,50 % w/w	0,02
- Sum of Impurities	Max 1,00 % w/w	0,04
RESIDUAL SOLVENTS (GC-HS)		
- Methylene Chloride	<= 50 ppm	0
- Ethyl Alcohol	<= 3000 ppm	9
- Toluene	<= 200 ppm	72
ASSAY (HPLC)	98,5 - 101,5 %w/w dry b	99,7
According to Eur.Ph.		
APPEARANCE	White crystalline powder	Compliant
IDENTIFICATION		
- IR Spectrum	Conforms to Ref. Std	Compliant
- Chemical Test	Positive	Compliant
SPECIFIC OPTICAL ROTATION (20°C)	115,0 - 120,0 Degree	117,2
APPEARANCE OF SOLUTION (5%, WATER)	Clear and Colourless	Compliant
pH (1%, WATER)	4,3 - 5,3	4,9
RELATED SUBSTANCES (HPLC)		
- "F" Impurity	<= 0,30 % w/w	0,00
- Max other related Impurity	<= 0,10 % w/w	0,05
- Sum of Impurities (Eur.Ph.)	<= 0,30 % w/w	0,05
HEAVY METALS (Limit Test)	Not more than 10ppm	Compliant
LOSS ON DRYING	<= 0,50 % w/w	0,21
SULPHATED ASH	<= 0,10 % w/w	0,02
NON AQUEOUS ASSAY	98,5 - 101,0 %w/w dry b	99,5

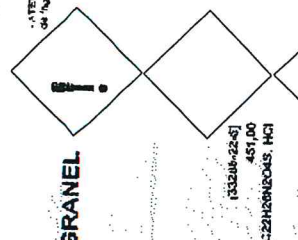
The lot complies with curr. USP & Eur.Ph

The Inspection lot was Approved on 06 May 2016 by Elena Rossi
Print date 27 Feb 2017

ORIGINAL

Quality Control

ATTENZIONE: I campioni devono essere conservati in luogo asciutto.



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03-03-2017 91151

DILTIAZEM CLH. GRANEL

8 432780 911511

Lote: 0065284

QC-00182495

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Additional Tests

TAPPED DENSITY	0,40 - 0,75 g/ml	0,60
PARTICLE SIZE		
- Smaller than 150 mcm	>= 90,0 %	91,3
- Smaller than 50 mcm	>= 50,0 %	51,7

Conforms to the Certificate of Suitability R1-CEP 1998-036 Rev.04 Issued on 12 July 2010

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