

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

Montecchio Headquarter:

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Lonigo plant:

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Share Capital E 10.000.000 i.v.

R.I. - C.F. & VAT NR. IT01712670247

M/V002266

R.E.A. Vicenza 179183

www.flsvl.com

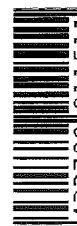
CERTIFICATE OF ANALYSIS

Material	7130000 DILTIAZEM HYDROCHLORIDE ✓	Batch	17A15A3618 ✓
Manuf.Date	14 Sep 2017	Retest Date	13 Sep 2022 ✓
Inspection Lot	080000008451		

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	111,9
LOSS ON DRYING	<= 0,50 % w/w	0,03
RESIDUE ON IGNITION	<= 0,10 % w/w	0,03
HEAVY METALS (Limit Test)	Not more than 20ppm	Compliant
RELATED COMPOUNDS (HPLC)		
- Desacetyl Diltiazem	Max 0,50 % w/w	0,03
- Max.Imp.other than Desacetyl DTZ	Max 0,50 % w/w	0,01
- Sum of impurities	Max 1,00 % w/w	0,05
RESIDUAL SOLVENTS (GC-MS)		
- Methylene Chloride	<= 50 ppm	0
- Ethyl Alcohol	<= 3000 ppm	1260
- Toluene	<= 200 ppm	79
ASSAY (HPLC)	98,5 - 101,5 %w/w dry b	99,4
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	116,2
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	0,06
- Sum of impurities (Eur.Ph.)	<= 0,30 % w/w	0,06
HEAVY METALS (Limit Test)	Not more than 10ppm	Compliant
LOSS ON DRYING	<= 0,50 % w/w	0,03
SULPHATED ASH	<= 0,10 % w/w	0,03
NON AQUEOUS ASSAY	98,5 - 101,0 %w/w dry b	99,9

The lot complies with curr. USP & Eur.Ph

ATTENZIONE: Questo prodotto è un medicinale. Leggere attentamente il foglio illustrativo. Se il sintomo persiste, consultare il medico. Il prodotto è sottoposto a controlli di qualità. Il prodotto è registrato in Italia e in altri paesi. Il prodotto è distribuito in Italia e in altri paesi. Il prodotto è distribuito in Italia e in altri paesi.

G
DILTIAZEM CLH. GRANELFecha Entrada: 26-01-2018
91151

8 432780 911511

Lote: 0073538



QC-00193240

[33284-22-5]
451,00
C22H18N2O4S · HClThe inspection lot was Approved on 09 Nov 2017 by Massimo Peruffo
Print date 19 Jan 2018

Quality Control

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Material 7130000 DILTIAZEM HYDROCHLORIDE

Batch

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Inspection Lot 080000008451

Characteristic**Specification****Results****Additional Tests**

TAPPED DENSITY

0,40 - 0,75 g/ml

0,55

PARTICLE SIZE

- Smaller than 150 mcm

>= 90,0 %

99,5

- Smaller than 50 mcm

>= 50,0 %

85,0

Conforms to the Certificate of Suitability R1-CEP 1998-036-Rev 05 issued on 1 March 2017

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