

Head Office: Viale Milano, 26 - 36075 Montebelluna Maggiore - Vicenza (Italy)

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Lonigo Plant: Via Dovaro, snc - 36045 Lonigo - Vicenza (Italy)

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CERTIFICATE OF ANALYSIS

CoA # 27207

Product: DILTIAZEM HYDROCHLORIDE**Chemical Name (IUPAC):** cis-(+)-3-(Acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)

-1,5-benzothiazepin-4(5H)-one, monohydrochloride

CAS NBR: 33286-22-5**Lot Number:** 201712014037**Code:** 7130000**Manufacturing date:** 14-November-2017**Retest Date :** 13-November-2022**Test Item:****Test Results:****Specifications:**

Diltiazem Trans Isomer	0.00% w/w	NMT 0.10% w/w
Max single unknown impurity	0.01% w/w	NMT 0.10% w/w
Max.Imp.other than Desacetyl DTZ	0.01% w/w	NMT 0.10% w/w
Sum of impurities	0.05% w/w	NMT 0.30% w/w
Methylene Chloride	Oppm	NMT 50ppm
Ethyl Alcohol	1109ppm	NMT 3000ppm
Toluene	67ppm	NMT 200ppm
ASSAY (HPLC)	100.8% w/w dry basis	98.5% w/w dry basis - 101.5% w/w dry basis
APPEARANCE OF SOLUTION (5%,WATER)	Compliant	Clear, colourless
pH (1%,WATER)	4.9	4.3 - 5.3
- "F" Impurity	0.00% w/w	NMT 0.30% w/w
Max other related impurity	0.00% w/w	NMT 0.10% w/w
Sum of impurities (Eur.Ph.)	0.00% w/w	NMT 0.30% w/w

FIS - FABBRICA ITALIANA SINTETICI S.p.A.**QUALITY CONTROL**

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99.7% w/w dry basis

98.5% w/w dry basis - 101.0% w/w dry basis

TAPPED DENSITY

0.57g/ml

0.40g/ml - 0.75g/ml

- Smaller than 150 mcm

94.9%

NLT 90%

- Smaller than 50 mcm

66.8%

NLT 50%

The lot complies with current USP, EP and Certificate of Suitability R1-CEP 1998-036-Rev 05 (issued on 1 March 2017)

Lot Approval Date: 18-December-2017

Control and manufacturing records have been reviewed according to FIS internal SOP and found to be in accordance with cGMPs, applicable laws and with all current documentation submitted by FIS to regulatory authorities or to the customer, in connection with marketing authorization.

QA release date: 20-December-2017

Certificate of Analysis was e-signed on 15-Jan-2018 by Massimo Peruffo Quality Control Manager

Certificate of Analysis was e-signed on 15-Jan-2018 by Daniela Quarzago Qualified Person

The information hereto reported is Confidential. Any disclosure to third parties should be approved by FIS.