



F.I.S. — Fabbrica Italiana Sintetici S.p.A.

Headquarters — Viale Milano, 26 — 36075 Montebelluna Maggiore (VI) — Italy
Lonigo site — Via Dovaro, snc — 36045 Lonigo (VI) — Italy — Ph. +39 0444 433111 — Fax +39 0444 831192

CERTIFICATE OF ANALYSIS

CoA # 39540

Product: DILTIAZEM HYDROCHLORIDE

Chemical Name (IUPAC): Clc(-c1cc(OC(=O)C)ccc1N(C)CC2=CC=CC=C2OC2)c3ccccc3
-1,5-benzothiazepin-4(5H)-one, monohydrochloride

CAS NBR: 33286-22-5

Lot Number: 202007034127

Code: 7130000

Manufacturing date: 02-July-2020

Retest Date: 01-July-2025

Test Item:

Test Results:

Specifications:

APPEARANCE

Compliant

White, crystalline powder

IDENT: IR Spectrum

Compliant

Comply to Ref. Standard

IDENT: HPLC Retention Time Value

Compliant

Comply to Ref. Standard

IDENT: Chemical Test (Eur. Ph.)

Compliant

Positive

SPECIFIC OPTICAL ROTATION (25°C) (USP)

115.1°

110.0° - 116.0°

SPECIFIC OPTICAL ROTATION (20°C) (Eur.Ph.)

119.4°

115.0° - 120.0°

LOSS ON DRYING (USP, Eur.Ph.)

0.15% w/w

NMT 0.50% w/w

RESIDUE ON IGNITION (Eur.Ph.)

0.03% w/w

NMT 0.10% w/w

HEAVY METALS (Limit Test) (Eur.Ph.)

Compliant

NMT 10 ppm

DTZ-62 (HPLC, USP)

<0.01% w/w

NMT 0.10% w/w

N-Acetyl Diltiazem (HPLC, USP)

<0.02% w/w

NMT 0.10% w/w

DTZ-61 (HPLC, USP)

<0.01% w/w

NMT 0.10% w/w

Desacetyl Diltiazem (HPLC, USP)

0.03% w/w

NMT 0.30% w/w

Fecha Entrada: 22-10-2020

91151

DILTIAZEM CLH

DILTIAZEM CLH



Lot: 0097908



QC-00225553

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Dilman 3

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CERTIFICATE OF ANALYSIS

CoA # 39540

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: 202007034127

Code: 7130000

Manufacturing date: 02-July-2020

Retest Date : 01-July-2025

Test Item:

Test Results:

Specifications:

Diltiazem Trans Isomer (HPLC, USP)	<0.01% w/w	NMT 0.10% w/w
Max single unknown impurity (HPLC, USP)	0.01% w/w	NMT 0.10% w/w
Max. Imp. other than Desacetyl DTZ (HPLC, USP)	0.01% w/w	NMT 0.10% w/w
Sum of impurities (HPLC, USP)	0.05% w/w	NMT 0.30% w/w
Methylene Chloride (GC-HS)	<4.9ppm	NMT 50ppm
Ethyl Alcohol (GC-HS)	1248ppm	NMT 3000ppm
Toluene (GC-HS)	83ppm	NMT 200ppm
ASSAY (USP, HPLC)(calc. on dry basis)	101.2% w/w	98.5% w/w - 101.5% w/w
APPEARANCE OF SOLUTION (5%, WATER) (Eur.Ph.)	Compliant	Clear, colourless
pH (1%, WATER) (Eur.Ph.)	4.8	4.3 - 5.3
"F" Impurity (HPLC, Eur.Ph.)	<0.05% w/w	NMT 0.30% w/w
Max other related impurity (HPLC, Eur.Ph.)	<0.05% w/w	NMT 0.10% w/w
Sum of impurities (HPLC, Eur.Ph.)	<0.05% w/w	NMT 0.30% w/w
NON AQUEOUS ASSAY (calc. on dry basis)	100.3% w/w	98.5% w/w - 101.0% w/w



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Code: 7130000

Manufacturing date: 02-July-2020

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Test Item:

Test Results:

Specifications:

TAPPED DENSITY (USP, Eur.Ph.)

0.54g/ml

0.40g/ml - 0.75g/ml

PSD (Laser): Smaller than 150 mcm

93%

NLT 90%

PSD (Laser): Smaller than 50 mcm

56%

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: 01-October-2020

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.

QA release date: 02-October-2020

Certificate of Analysis was e-signed on 02-Oct-2020 by Massimo Peruffo Quality Control Manager

Certificate of Analysis was e-signed on 06-Oct-2020 by Elisa Paganello Qualified Person

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