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

Headquarters — Viale Milano, 26 — 36075 Montecchio 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): 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:*
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.
8 432780 911511
Lote: 0097908
QC-00225553

Guinama S.L.U
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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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Manufacturing date: 02-July-2020

Retest Date : 01-July-2025

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