



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

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

CERTIFICATE OF ANALYSIS

CoA # 57058

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: 202311034084

Code: 7130000

Manufacturing date: 14-November-2023

Retest Date : 12-November-2028

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)	114.1°	110.0° - 116.0°
SPECIFIC OPTICAL ROTATION (20°C) (Eur.Ph.)	118.9°	115.0° - 120.0°
LOSS ON DRYING (USP, Eur.Ph.)	0.04% w/w	NMT 0.50% w/w
RESIDUE ON IGNITION (Eur.Ph.)	0.01% w/w	NMT 0.10% w/w
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)	0.04% w/w	NMT 0.30% w/w
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



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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)	1604ppm	NMT 3000ppm
Toluene (GC-HS)	110ppm	NMT 200ppm
ASSAY (USP, HPLC)(calc. on dry basis)	100.0% 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)	100.2% w/w	98.5% w/w - 101.0% w/w
TAPPED DENSITY (USP, Eur.Ph.)	0.63g/ml	0.40g/ml - 0.75g/ml
PSD (Laser): Smaller than 150 mcm	96%	NLT 90%



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Code: 7130000

Manufacturing date: 14-November-2023

Retest Date: 12-November-2028

Test Item:

Test Results:

Specifications:

PSD (Laser): Smaller than 50 mcm

66%

NLT 50%

The lot complies with current USP, EP and Certificate of Suitability R1-CEP 1998-036-Rev 07 (Issued on 15 March 2022)

Lot Approval Date: 15-December-2023

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: 15-December-2023

Certificate of Analysis was e-signed on 08-Jan-2024 10:39 by Massimo Peruffo Quality Control Manager

Certificate of Analysis was e-signed on 08-Jan-2024 11:24 by Daniela Quarzago Qualified Person

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

Fecha Entrada: 06-02-2024
91151
DILTIAZEM CLH. GRANEL
8 432780 911511
Lote: 0125133
33286-22-5
451,00
C22H28N2O4S.HCl
Bultos: 3
Guinama S.L.U.
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45102 La Pobla de Vallbona (Spain)
Tel.: +34 93 186 90 33 - www.guinama.com

• PELIGRO: H302 Noctro en caso de ingestión. H318 Provoca lesiones oculares graves. H361d No se sospecha que dañe al feto. P201+P202 Llevarse las manos limpias después de la manipulación. P273 No comer, beber ni fumar durante su utilización. P280 Llevar guantes, protección ocular, mascarilla de protección. P301+P312 EN CASO DE INGESTIÓN: Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico si se encuentra mal. P305+P351+P338 EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir señalando. P308+P313 EN CASO DE exposición manifestada o sospecha: Consultar a un médico. P310 Lla