



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# 46777

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: 202201104111

Code: 7130000

Manufacturing date: 10-January-2022

Retest Date: 09-January-2027

Test Item:

Test Results:

Specifications:

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)	0.14% w/w	NMT 0.30% w/w
Methylene Chloride (GC-HS)	<4.9ppm	NMT 50ppm
Ethyl Alcohol (GC-HS)	1074ppm	NMT 3000ppm
Toluene (GC-HS)	115ppm	NMT 200ppm
ASSAY (USP, HPLC)(calc. on dry basis)	100.4% 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.)	0.10% 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.)	0.10% 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.)	0.55g/ml	0.40g/ml - 0.75g/ml



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Specifications:

PSD (Laser): Smaller than 150 mcm

98%

NLT 90%

PSD (Laser): Smaller than 50 mcm

75%

NLT 50%

The lot complies with current USP, EP and Certificate of Suitability R1-CEP 1998-036-Rev 06 (issued on 17 December 2020)

Lot Approval Date: 09-February-2022

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: 09-February-2022

Certificate of Analysis was e-signed on 09-Feb-2022 by Massimo Peruffo Quality Control Manager

Certificate of Analysis was e-signed on 10-Feb-2022 by Daniela Quarzago Qualified Person

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