

CERTIFICATE OF ANALYSIS

1(3)

Timolol maleate

Batch No. : 21007112 ✓

Mfg. date : 17/05/2021

Control No. : 2101497

Retest date : 17/05/2026 ✓

Released date : 24/06/2021

Storage : Max 25°C / excursions up to 40 °C. Protected from light.

Specifications: PCAS Finland, Ph.Eur., USP

TESTS

LIMITS

RESULTS

NOTES

CHARACTERS

Description

A white or almost white, Complies
crystalline powder or
colourless crystals

IDENTIFICATION

Identification by specific optical rotation

Positive

Complies

Identification by IR (USP)

Positive

Complies

Identification by HPLC

Positive

Complies

Identification by IR (Ph.Eur.)

Positive

Complies

Nº lote ACOFARMA:

222719

Firma y fecha:

J. J. J.
11/05/22

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TESTS	LIMITS	RESULTS	NOTES
TESTS			
✓ Clarity of solution / Appearance of solution	Clear	Complies	
✓ Color of solution / Appearance of solution	Not more intensely coloured than reference solution B8	Complies	
✓ pH	3.8 - 4.3	4.0	
✓ Specific optical rotation (Ph.Eur.)	-6.2 - -5.7 °	-6.1	°
✓ Loss on drying according to USP	NMT 0.5 %	0.07	%
✓ Loss on drying according to Ph. Eur.	NMT 0.5 %	0.08	%
✓ Residue on ignition, sulfated ash	NMT 0.1 %	Complies	
✓ (R)-isomer (Enantiomeric purity)	NMT 0.4 %	0.07	%
✓ Impurity B (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Impurity C (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Impurity D (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Impurity E (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Impurity F (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Any unspecified impurity (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%
✓ Total impurities (LOD=0.025 %, LOQ=0.05 %)	NMT 0.2 %	0	%
Timolol related compound B	NMT 0.4 %	0	%
Timolol bithiadiazol analog	NMT 0.4 %	0	%
Timolol related compound D	NMT 0.4 %	0	%
Timolol maleate ester	NMT 0.4 %	0	%
Timolol related compound F	NMT 0.4 %	0	%
Any unspecified impurity	NMT 0.10 %	0	%
Total impurities	NMT 1.0 %	0	%
✓ Methylene chloride (Residual solvents)	NMT 60 ppm	0	ppm

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3(3)

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<u>TESTS</u>	<u>LIMITS</u>	<u>RESULTS</u>		<u>NOTES</u>
✓ Hexane (Residual solvents)	NMT 250 ppm	0	ppm	(LOD=150 ppm, LOQ=205 ppm)
✓ Toluene (Residual solvents)	NMT 150 ppm	0	ppm	(LOD=20 ppm, LOQ=40 ppm)
ASSAY				
✓ Assay by titration / dried substance	98.5 - 101.0 %	100.7	%	
Assay by HPLC / dried basis	98.0 - 102.0 %	99.9	%	
MICROBIOLOGICAL TESTS				
Total aerobic microbial count (TAMC)	NMT 10 CFU/g	Complies		
Total combined yeast/moulds count (TYMC)	NMT 10 CFU/g	Complies		

A result 0 (zero) means $\leq$ LOD or/and $<$ LOQ.

This batch has been manufactured according to cGMP requirements.

This batch fulfils the specification.

Reference : 24319

Notes no: 265/22

Date : 03/05/2022



QUALITY ASSURANCE
PCAS Finland Oy

