SEQENS

CERTIFICATE OF ANALYSIS

Timolol maleate

Batch No. : 20014761 **Mfg. date :** 29/10/2020

Control No. : 2003246 **Retest date :** 29/10/2025

Released date : 27/11/2020

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, crystalline powder or colourless crystals	Complies	
IDENTIFICATION			
Identification by specific optical rotation	Positive	Complies	
Identification by IR (USP)	Positive	Complies	
Identification by IR (Ph.Eur.)	Positive	Complies	
Identification by HPLC	Positive	Complies	

Nº lote ACOFARMA: 213338

Firma y fecha: 17/06/21

SEQENS

Nº lote ACOFARMA: 213338
Firma y fecha: 17/06/21

CERTIFICATE OF ANALYSIS

Timolol maleate

Batch No. : 20014761

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		
ecific optical rotation (Ph.Eur.)	-6.2 - -5.7 °	-6.1	°	
Loss on drying according to USP	NMT 0.5 %	0.06	%	
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.09	%	
Residue on ignition, sulfated ash	NMT 0.1 %	Complies		
(R)-isomer (Enantiomeric purity)	NMT 0.4 %	0.06	%	LOD=0.03 %, LOQ=0.06 %
Impurity B (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
Impurity C (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
Impurity D (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
Impurity E (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
Impurity F (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
Any unspecified impurity (LOD=0.025 %, LOQ=0.05 %)	NMT 0.10 %	0	%	Related substances by HPLC
al impurities (LOD=0.025 %, LOQ=0.05 %)	NMT 0.2 %	0	%	Related substances by HPLC
Timolol related compound B	NMT 0.4 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Timolol bisthiadiazol analog	NMT 0.4 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Timolol related compound D	NMT 0.4 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Timolol maleate ester	NMT 0.4 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Timolol related compound F	NMT 0.4 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Any unspecified impurity	NMT 0.10 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Total impurities	NMT 1.0 %	0	%	Organic impurities by HPLC (LOD=0.03%, LOQ=0.05%)
Methylene chloride (Residual solvents)	NMT 60 ppm	0	ppm	(LOD=25 ppm, LOQ=50 ppm)

SEQENS

CERTIFICATE OF ANALYSIS 3(3)

Timolol maleate

Batch No. : 20014761

TESTS	LIMITS	RESULTS		NOTES
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 %	98.9	%	
Assay by HPLC / dried basis	98.0 - 102.0 %	99.8	%	
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 ≤ LOD or/and < LOQ.

This batch has been manufactured according to cGMP requirements.

This batch fulfils the specification.

Reference : 19232

Notes no: 303/21

Date : 09/06/2021

QUALITY ASSURANCE
PCAS Finland Oy

Nº lote ACOFARMA: 213338

Firma y fecha: 17/06/21