

CERTIFICATE OF ANALYSIS

1(3)

Timolol maleate

Batch No. : 19002461

Mfg. date : 11/02/2019

Control No. : 1900553

Retest date : 11/02/2024

Released date : 15/03/2019

Storage : Max 25 °C / excursions up to 40 °C

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 IR (Ph.Eur.)

Positive

Complies

Identification by HPLC

Positive

Complies

CERTIFICATE OF ANALYSIS

2(3)

Timolol maleate

Batch No. : 19002461

<u>TESTS</u>	<u>LIMITS</u>	<u>RESULTS</u>	<u>NOTES</u>
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	3.9	
Specific optical rotation (Ph.Eur.)	-6.2 - -5.7 °	-6.0	°
Loss on drying according to USP	NMT 0.5 %	0.02	%
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.05	%
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 (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%
Timolol related compound C (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%
Timolol related compound D (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%
Timolol related compound E (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%
Timolol related compound F (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%
Any unspecified impurity (LOD=0.03%, LOQ=0.05%)	NMT 0.10 %	0	%
Total impurities (LOD=0.03%, LOQ=0.05%)	NMT 1.0 %	0	%
Methylene chloride (Residual solvents)	NMT 60 ppm	0	ppm

(LOD=25 ppm, LOQ=50 ppm)

CERTIFICATE OF ANALYSIS

3(3)

Timolol maleate

Batch No. : 19002461

<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 %	99.8 %
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 : 10410

Notes no: 702/19

Date : 21/11/2019



QUALITY ASSURANCE
PCAS Finland Oy