

CERTIFICATE OF ANALYSIS

1(3)

Timolol maleate

Batch No. : 20007484

Mfg. date : 19/05/2020

Control No. : 2001672

Retest date : 19/05/2025

Released date : 18/06/2020

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

Specifications: PCAS Finland, Ph.Eur., USP

<u>TESTS</u>	<u>LIMITS</u>	<u>RESULTS</u>	<u>NOTES</u>
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



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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 °	-6.0	
Loss on drying according to USP	NMT 0.5 %	0.00	%
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.02	%
Residue on ignition, sulfated ash	NMT 0.1 %	Complies	
(R)-isomer (Enantiomeric purity)	NMT 0.4 %	0.07	% 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
Total 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 bistiadiazol 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)

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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 %	99.6 %	
Assay by HPLC / dried basis	98.0 - 102.0 %	99.5 %	
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 : 16228

Notes no: 684/20

Date : 23/11/2020



QUALITY ASSURANCE
PCAS Finland Oy

Nº lote ACOFARMA:
202305

Firma y fecha: Mela
01/12/20