N° LOTE ACOFARMA 181186

pcas FINLAND

CERTIFICATE OF ANALYSIS

Timolol maleate

Batch No. : 18002778 **Mfg. date :** 21/08/2018

Control No. : 1802685 **Retest date :** 21/08/2023

Released date : 20/09/2018

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, 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	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 °	-6.0	°	
Loss on drying according to USP	NMT 0.5 %	0.06	%	
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.04	%	
Residue on ignition, sulfated ash	NMT 0.1 %	Complies		
Heavy metals	NMT 0.002 %	NMT 0.001 %		
(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
y 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 (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%	Organic impurities by HPLC
Timolol related compound C (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%	Organic impurities by HPLC
Timolol related compound D (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%	Organic impurities by HPLC
Timolol related compound E (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%	Organic impurities by HPLC
Timolol related compound F (LOD=0.03%, LOQ=0.05%)	NMT 0.4 %	0	%	Organic impurities by HPLC
Any unspecified impurity (LOD=0.03%, LOQ=0.05%)	NMT 0.10 %	0	%	Organic impurities by HPLC
Total impurities (LOD=0.03%, LOQ=0.05%)	NMT 1.0 %	0	%	Organic impurities by HPLC
Methylene chloride (Residual solvents)	NMT 60 ppm	0	ppm	(LOD=25 ppm, LOQ=50 ppm)

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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 %	100.0	%	
Assay by HPLC / dried basis	98.0 - 102.0 %	100.8	%	
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 : 3724

Notes no: 712/18

Date : 02/11/2018

QUALITY ASSURANCE
PCAS Finland Oy

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