Lote Acofarma: 161398

pcas FINLAND

CERTIFICATE OF ANALYSIS

Timolol maleate

Batch No. : 77510D003 **Mfg. date :** 22/05/2016

Control No. : 1601698 **Retest date :** 22/05/2021

Released date : 15/06/2016

Storage : -

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 UV	Positive	Complies	
Identification by HPLC	Positive	Complies	

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LOT ACOF30215: 161398

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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 / dry substance (USP)	-12.5 - -11.7 °	-11.9	°	
Specific optical rotation (Ph.Eur.)	-6.2 - -5.7 °	-6.1	°	
Loss on drying according to USP	NMT 0.5 %	0.01	%	
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.02	%	
Residue on ignition	NMT 0.1 %	Complies		
Heavy metals	NMT 0.002 %	NMT 0.001 %		
(R)-isomer (Enantiomeric purity)	NMT 0.4 %	0.08	%	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 (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

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NOTE ACOFARMS: 161398

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TESTS	LIMITS	RESULTS		NOTES
Methylene chloride (Residual solvents)	NMT 60 ppm	0	ppm	(LOD=25 ppm, LOQ=50 ppm)
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 %	99.5	%	
Assay by HPLC / dried basis	98.0 - 102.0 %	100.5	%	

A result 0 (zero) means ≤ LOD or/and < LOQ.

This batch has been manufactured according to cGMP requirements.

This batch fulfils the specification.

Reference : 44698

Notes no: 621/16

Date : 08/09/2016

Laimmy Salonmaa

QUALITY ASSURANCE
PCAS Finland Oy