

CERTIFICATE OF ANALYSIS

1(3)

Timolol maleate

Batch No. : 77510D006

Mfg. date : 30/11/2016

Control No. : 1603713

Retest date : 30/11/2021

Released date : 20/12/2016

Storage : -

Specifications: PCAS Finland, Ph.Eur., USP

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

Description	A white or almost white, crystalline powder or colourless crystals		
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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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2(3)

Timolol maleate

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<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 / 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 %	0.02	%
Loss on drying according to Ph. Eur.	NMT 0.5 %	0.08	%
Residue on ignition	NMT 0.1 %	Complies	
Heavy metals	NMT 0.002 %	NMT 0.001 %	
(R)-isomer (Enantiomeric purity)	NMT 0.4 %	0.09	%
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	%

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3(3)

Timolol maleate

Batch No. : 77510D006

<u>TESTS</u>	<u>LIMITS</u>	<u>RESULTS</u>	<u>NOTES</u>
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 %	99.9 %
Assay by HPLC / dried basis	98.0 - 102.0 %	99.7 %

A result 0 (zero) means $\leq$ LOD or/and $<$ LOQ.

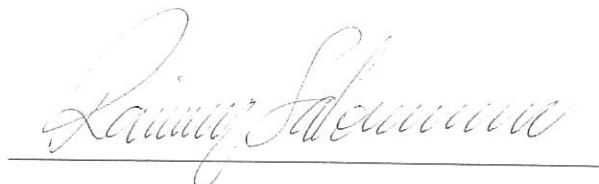
This batch has been manufactured according to cGMP requirements.

This batch fulfils the specification.

Reference : 45060

Notes no: 224/17

Date : 03/04/2017

**QUALITY ASSURANCE**
PCAS Finland Oy