

Ciserano, 26/10/2018

ANALYSIS No. F535/2018
BATCH No. 109118009

Manufacturing date: **July 2018**

Retest date: **July 2023**

Batch size: **491,00 Kg**
PRODUCT
ATENOLOL USP / PH. EUR.
CAS N. 29122-68-7
Physical State: powder

Molecular weight: 266.3

Colour: white or almost white

Formula : C₁₄H₂₂N₂O₃
Odour: odourless

Method No. 1091/1

Solubility: Sparingly sol. in Water, sol. in Absolute Ethanol, slightly sol. in Dichloromethane
 and pract. insol. in Ether.

DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. spectrum	Positive	Positive	Positive	
Ratio Abs 275 / Abs 282	1.18	Positive	min. 1,15 max. 1,20	
Melting point	152.8 °C - 153.5 °C	min. 152°C max. 156,5°C	min. 152°C max. 155°C	
Loss on drying	0.22 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.069 %	n.m.t. 0,2%	n.m.t. 0,1%	
ASSAY				
HClO ₄ 0,1N (on dried substance)	99.83 %		min 99,0% max 101,0%	
HPLC (on dried substance)	99.58 %	min. 98,0% max. 102,0%		
HPLC IN HOUSE METHOD				
Impurities List				
Fumaric acid	0.02 %			n.m.t. 0,1%
Diol	0.06 %		n.m.t. 0,2%	
4-Hydroxyphenylacetamide	0.01 %		n.m.t. 0,10%	
Atenolol epoxyde	0.02 %		n.m.t. 0,10%	
Bis ether	0.02 %		n.m.t. 0,10%	
Chloridrine	Not detectable		n.m.t. 0,10%	
Teramine	0.06 %		n.m.t. 0,1%	
Blocker Acid	0.06 %		n.m.t. 0,1%	
Atenolol Nitrile	Not detectable		n.m.t. 0,10%	
Unknown Impurity Max	0.05 %		n.m.t. 0,10%	

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Total Impurities	0.40 %		n.m.t. 0,5%	
USP METHOD				
Impurities List				
Fumaric Acid	0.02 %			n.m.t. 0,1%
Diol	0.06 %			n.m.t. 0,2%
4-Hydroxyphenylacetamide	0.01 %	n.m.t. 0,25%		n.m.t. 0,10%
Atenolol epoxyde	0.02 %	n.m.t. 0,25%		n.m.t. 0,10%
Bis ether	0.05 %	n.m.t. 0,25%		n.m.t. 0,10%
Chloridine	0.02 %	n.m.t. 0,25%		n.m.t. 0,10%
Teramine	0.02 %	n.m.t. 0,25%		n.m.t. 0,1%
Blocker Acid	Not detectable	n.m.t. 0,25%		n.m.t. 0,1%
Atenolol Nitrile	Not detectable	n.m.t. 0,25%		n.m.t. 0,10%
Unknown impurity Max	0.05 %	n.m.t. 0,1%		n.m.t. 0,10%
Total Impurities	0.24 %	n.m.t. 0,5%		
Chlorides	Not detectable	n.m.t. 0,1%	n.m.t. 0,1%	
Angle of optical rotation (1% in water) (1 dm tube)	0.0018 °		min. -0,10° max. +0,10°	min. -0,025° max. +0,025°
Clarity of solution	Clear		Clear	
Colour of solution	n.m.t. yellow degree 6		n.m.t. degree 6	

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Colour: white or almost white		Formula : C ₁₄ H ₂₂ N ₂ O ₃		
Odour: odourless		Method No. 1091/1		
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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
FOREIGN SUBSTANCES				
Powders	n.m.t. 10 ppm			n.m.t. 10 ppm
Particle size	98.5 %			n.l.t. 80% passes 105 mcm
(Malvern - Scirocco 2000)	100.0 %			n.l.t. 85% passes 1000 mcm
Bulk density	0.40 g/ml			min. 0.25 g/ml max. 0.45 g/ml
Tapped density	0.50 g/ml			min. 0.40 g/ml max. 0.60 g/ml
RESIDUAL SOLVENTS				
Isopropylamine	12.1 ppm			n.m.t. 100 ppm
1-Methoxy-2-propanol	2.2 ppm			n.m.t. 100 ppm

We hereby certify that the material identified above has been analysed and found in accordance with the specifications of USP and Ph. Eur..

Qualified Person


Release date: 13/09/2018

Quality Control Manager
