

Ciserano, 22/02/2017

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ANALYSIS No. F582/2016
BATCH No. 102816031

Manufacturing date: September 2016

Retest date: September 2021

Batch size: 1163,00 Kg

PRODUCT
PROPRANOLOL HYDROCHLORIDE USP / PH. EUR.
CAS N. 318-98-9
Physical State: crystalline powder

Molecular weight: 295.81

Colour: white to off-white

Formula : C₁₆H₂₁NO₂.HCl

Odour: odourless

Method No. 1028/1

Solubility: Soluble in water and Ethanol 96%, slightly soluble in Chloroform and practically insoluble in Ether.

DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. spectrum	Positive	Positive	Positive	
HPLC	Positive	Positive		
Chlorides test	Positive	Positive	Positive	
Melting point	163.5 °C - 164.0 °C	min. 162 °C max. 165 °C	min. 163°C max. 166°C	
Acidity or alkalinity	Conform		Conform	
Clarity and colour of solution (10% in methanol)	Clear n.m.t. brown-yellow degree 6		Clear n.m.t. degree 6	
Heavy metals	n.m.t. 20 ppm		n.m.t. 20 ppm	
Loss on drying	0.28 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.093 %	n.m.t. 0,1%	n.m.t. 0,1%	
ASSAY				
NaOH 0,1N (on dried substance)	100.04 %		min. 99,0% max. 101,0%	
HPLC (on dried substance)	100.07 %	min. 98,0% max. 101,5%		
Related substances (HPLC)				
Labelled Impurities				
Diol	Not detectable		n.m.t. 0,10%	
Teramine	0.01 %		n.m.t. 0,10%	
Bis ether	Not detectable		n.m.t. 0,10%	
Unknown Impurity Max	Not quantifiable		n.m.t. 0,10%	
Total Impurities	0.02 %		n.m.t. 0,4%	

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
<i>Specific rotation</i> (4% in water)	-0.2352 °	-1,0°/+1,0°		
FOREIGN SUBSTANCES <i>Powders</i>	n.m.t. 15 ppm			n.m.t. 15 ppm
<i>Particle size</i>	80.4 %			n.l.t. 50% passes 53 mcm
<i>Bulk density</i>	0.29 g/ml			min. 0,25 g/ml max. 0,45 g/ml
<i>Tapped density</i>	0.48 g/ml			min. 0,40 g/ml max. 0,60 g/ml
RESIDUAL SOLVENTS <i>Acetone</i> <i>Toluene</i>	76.6 ppm Not detectable			n.m.t. 500 ppm n.m.t. 300 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

Quality Control Manager

Release date: 19/12/2016