

Ciserano, 22/02/2017

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>I.R. spectrum</i>	Positive	Positive	Positive	
<i>HPLC</i>	Positive	Positive		
<i>Chlorides test</i>	Positive	Positive	Positive	
<i>Melting point</i>	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				
<i>NaOH 0,1N (on dried substance)</i>	100.04 %		min. 99,0% max. 101,0%	
<i>HPLC (on dried substance)</i>	100.07 %	min. 98,0% max. 101,5%		
Related substances (HPLC)				
Labelled Impurities				
<i>Diol</i>	Not detectable		n.m.t. 0,10%	
<i>Teramine</i>	0.01 %		n.m.t. 0,10%	
<i>Bis ether</i>	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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Specific rotation (4% in water)	-0.2352 °	-1,0°/+1,0°		
FOREIGN SUBSTANCES Powders	n.m.t. 15 ppm			n.m.t. 15 ppm
Particle size	80.4 %			n.l.t. 50% passes 53 mcm
Bulk density	0.29 g/ml			min. 0,25 g/ml max. 0,45 g/ml
Tapped density	0.48 g/ml			min. 0,40 g/ml max. 0,60 g/ml
RESIDUAL SOLVENTS Acetone	76.6 ppm			n.m.t. 500 ppm
Toluene	Not detectable			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