

Ciserano, 31/10/2019				
ANALYSIS No. F604/2019		BATCH No. 102819032		
Manufacturing date: July 2019		Retest date: July 2024		Batch size: 907,00 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	163.0 °C - 163.5 °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	
Loss on drying	Not detectable	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.076 %	n.m.t. 0,1%	n.m.t. 0,1%	
ASSAY				
NaOH 0,1N (on dried substance)	99.14 %		min. 99,0% max. 101,0%	
HPLC (on dried substance)	99.19 %	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 quantifiable		n.m.t. 0,10%	
Unknown Impurity Max	0.01 %		n.m.t. 0,10%	
Total Impurities	0.03 %		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)	-0.1598 °	-1,0°/+1,0°		
FOREIGN SUBSTANCES <i>Powders</i>	n.m.t. 15 ppm			n.m.t. 15 ppm
<i>Particle size</i>	54.2 %			n.l.t. 50% passes 53 mcm
<i>Bulk density</i>	0.32 g/ml			min. 0,25 g/ml max. 0,45 g/ml
<i>Tapped density</i>	0.56 g/ml			min. 0,40 g/ml max. 0,60 g/ml
RESIDUAL SOLVENTS <i>Acetone</i>	Not quantifiable			n.m.t. 500 ppm
<i>Toluene</i>	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


Release date: 06/11/2019

Quality Control Manager
