

METAPHARMACEUTICAL

N DE LOTE:

0220322

COSMA S.p.A.

Società con socio unico

Cap. Soc. € 954.600 i.v. - Cod. Fisc. / Part. IVA IT 00714610169

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25 MAR. 2022

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Ciserano, 01/10/2021				
ANALYSIS No. F693/2021		BATCH No. 102821029		
Manufacturing date: May 2021		Retest date: May 2026		Batch size: 1093,00 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 and Heptane				
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	163.1 °C - 163.4 °C		min. 163°C max. 166°C	min. 163°C max. 165°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. brown-yellow degree 6	
Loss on drying	0.07 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.024 %	n.m.t. 0,1%	n.m.t. 0,1%	
ASSAY				
NaOH 0,1N (on dried substance)	100.05 %		min. 99,0% max. 101,0%	
HPLC (on dried substance)	100.55 %	min. 98,0% max. 102,0%		
Related substances (HPLC)				
Labelled Impurities				
Diol	Not quantifiable	n.m.t. 0,1%	n.m.t. 0,10%	
Teramine	0.01 %	n.m.t. 0,1%	n.m.t. 0,10%	
Bis ether	Not quantifiable	n.m.t. 0,1%	n.m.t. 0,10%	
Unknown Impurity Max	0.01 %	n.m.t. 0,10%	n.m.t. 0,10%	
Total Impurities	0.04 %	n.m.t. 0,4%	n.m.t. 0,2%	

Qualified Person

Quality Control Manager

Ciserano, 01/10/2021

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Odour: odourless

Method No. 1028/1

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
FOREIGN SUBSTANCES				
<i>Powders</i>	n.m.t. 15 ppm			n.m.t. 15 ppm
<i>Particle size</i>	53.4 %			n.l.t. 50% passes 53 mcm
<i>Bulk density</i>	0.27 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>	Not quantifiable			n.m.t. 500 ppm
<i>Toluene</i>	Not detectable			n.m.t. 300 ppm
<i>Residual Epichlorohydrin</i>	Not performed			n.m.t. 3.75 ppm
<i>Non routine determination</i>				
<i>Residual PPEP2</i>	Not performed			n.m.t. 3.75 ppm
<i>Non routine determination</i>				
<i>Residual 1-Naphtol and 2-Naphtol</i>				
<i>1-Naphtol Content</i>	Not performed			n.m.t. 1000 ppm
<i>2-Naphtol Content</i>	Not performed			n.m.t. 1000 ppm
<i>Non routine determination</i>				

Qualified Person

Quality Control Manager



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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Residual Benzene Non routine determination	Not performed			n.m.t. 2 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: 06/10/2021