



COSMA S.p.A.

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Società con socio unico
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Cisearno, 19/11/2020

ANALYSIS No. F785/2020

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BATCH No. 102820032

Manufacturing date: September 2020		Release date: September 2025		Batch size: 654,00 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		
HPPLC	Positive	Positive	Positive		
Chlorides test	Positive	Positive	Positive		
Melting point	163.0 °C - 164.6 °C		Positive min. 163°C max. 166 °C		
Acidity or alkalinity	Conform		Conform		
Clarity and colour of solution (10% in methanol)	Clear n.m.l. brown-yellow degree 6		Clear n.m.l. degree 6		
Loss on drying	0.04 %	n.m.l. 0,5%	n.m.l. 0,5%		
Sulphated ash	0.051 %	n.m.l. 0,1%	n.m.l. 0,1%		
ASSAY					
NaOH 0,1N (on dried substance)	100,45 %		min. 99,0% max. 101,0%		
HPPLC (on dried substance)	99.67 %	min. 98,0% max. 102,0%			
Related substances (HPPLC)					
Labelled Impurities					
Diol	Not quantifiable		n.m.l. 0,10%		
Termination	0.03 %		n.m.l. 0,10%		
Bis ether	0.01 %		n.m.l. 0,10%		
Unknown Impurity Max	0.01 %		n.m.l. 0,10%		
Total Impurities	0.05 %		n.m.l. 0,2%		

Qualified Person
G. Basso

Quality Control Manager
G. Basso

Ciserano, 19/11/2020 ANALYSIS No. F785/2020		BATCH No. 102820032	
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DETERMINATIONS		RESULTS	LIMITS USP
FOREIGN SUBSTANCES Powders		n.m.t. 15 ppm	LIMITS EP
Particle size		88.7 %	IN-HOUSE LIMITS
Bulk density		0.30 g/ml	n.m.t. 15 ppm
Tapped density		0.53 g/ml	n.l.t. 50% passes 53 µm
RESIDUAL SOLVENTS Acetone Toluene		Not quantifiable Not detectable	min. 0.25 g/ml max. 0.45 g/ml min. 0.40 g/ml max. 0.60 g/ml

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
[Signature]

Quality Control Manager
[Signature]

Release date: 18/11/2020