

Ciserano, 14/09/2020				
ANALYSIS No. F542/2020		BATCH No. 102820018		
Manufacturing date: June 2020		Retest date: June 2025		Batch size: 1138,00 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	163.5 °C - 164.1 °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	0.10 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.044 %	n.m.t. 0,1%	n.m.t. 0,1%	
ASSAY				
NaOH 0,1N (on dried substance)	100.61 %		min. 99,0% max. 101,0%	
HPLC (on dried substance)	99.74 %	min. 98,0% max. 102,0%		
Related substances (HPLC)				
Labelled Impurities				
Diol	Not detectable	n.m.t. 0,1%	n.m.t. 0,10%	
Teramine	0.02 %	n.m.t. 0,1%	n.m.t. 0,10%	
Bis ether	0.01 %	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	0.05 %	n.m.t. 0,4%	n.m.t. 0,2%	

Qualified Person

Quality Control Manager

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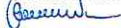
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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
FOREIGN SUBSTANCES				
<i>Powders</i>	n.m.t. 15 ppm			n.m.t. 15 ppm
<i>Particle size</i>	82.2 %			n.l.t. 50% passes 53 mcm
<i>Bulk density</i>	0.29 g/ml			min. 0,25 g/ml max. 0,45 g/ml
<i>Tapped density</i>	0.56 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
<i>Residual Epichlorohydrin</i> <i>Non routine determination</i>	Non routinary test			n.m.t. 3.75 ppm
<i>Residual PPEP2</i> <i>Non routine determination</i>	Non routinary test			n.m.t. 3.75 ppm
<i>Residual 1-Naphtol and 2-Naphtol</i> <i>1-Naphtol Content</i> <i>2-Naphtol Content</i> <i>Non routine determination</i>	Non routinary test Non routinary test			n.m.t. 1000 ppm n.m.t. 1000 ppm

Qualified Person



Quality Control Manager





COSMA S.p.A.

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Società con socio unico

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

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Ciserano, 14/09/2020

Page 3 / 3

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Residual Benzene Non routine determination	Non routine test			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

Release date: 16/09/2020

Quality Control Manager