

CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

Prodotto - Product: 001907_007 PROPRANOLOLO CLORIDRATO - PROPRANOLOL HYDROCHLORIDE - PROPRANOLOLI HYDROCHLORIDUM

Conformità - Compliance: EP

Lotto - Batch Number: F2400149

Produttore - Manufacturer: Farmalabor Srl, Via Pozzillo Z.I., 76012 Canosa di Puglia (BT), Italia

Data produzione - Manufacturing date: 13/08/2024

Data scadenza - Expiry date: 10/01/2029

Data di analisi - Analysis date: 20/08/2024

Produttore Materia Prima COSMA S.p.A. - Italia
Raw material manufacturer: Via Colleoni, 15/17 - 24040 Ciserano (BG)

Lotto produttore materia prima - Raw material manufacturer batch number: 202400175/102824005

La materia prima è stata autorizzata dall' AIFA (Agenzia Italiana del Farmaco) ad essere ripartita presso l'officina farmaceutica Farmalabor.

Farmalabor repackaging activity of this raw material is licensed by AIFA (Agenzia Italiana del Farmaco)

NOME CHIMICO	(2RS)-1-[(Propan-2-il)ammino]-3-[(naftalen-1-il)ossi]propan-2-olo cloridrato	CHEMICAL NAME	(2RS)-1-[(Propan-2-yl)amino]-3-[(naphthalen-1-yl)oxy]propan-2-ol hydrochloride
NUMERO CAS	318-98-9	CAS NUMBER	318-98-9
FORMULA MOLECOLARE	C16H21NO2 · HCl	MOLECULAR FORMULA	C16H21NO2 · HCl
PESO MOLECOLARE	295.8 g/mol	MOLECULAR WEIGHT	295.8 g/mol

ANALISI MATERIA PRIMA	SPECIFICHE	RISULTATI	RAW MATERIAL ANALYSIS	SPECIFICATIONS	RESULTS
PH.EUR.			PH.EUR.		
ASPETTO	Polvere cristallina bianca o quasi bianca	Conforme	ASPEAREANCE	White or almost white, crystalline powder	Complies
SOLUBILITA'	Solubile in acqua ed in etanolo (96%)	Conforme	SOLUBILITY	Soluble in water and in ethanol (96%)	Complies
IDENTIFICAZIONE	Praticamente insolubile in eptano	Conforme	IDENTIFICATION	Practically insoluble in heptane	Complies
	IR: Conforme	Conforme		IR: Complies	Complies
	Cloruri: Conforme	Conforme		Chlorides: Complies	Complies
ASPETTO DELLA SOLUZIONE	Limpida e non superiore al grado 6	Conforme	ASPEAREANCE OF SOLUTION	Clear and not more than degree 6	Complies
ACIDITA' O ALCALINITA'	Conforme	Conforme	ACIDITY OR ALKALINITY	Complies	Complies
SOSTANZE CORRELATE (HPLC)	Impurezze non specificate: max 0.10%	< 0,05	RELATED SUBSTANCES (HPLC)	Any unspecified impurity: max 0.10%	< 0,05
	Tot. imp.: Max 0.2%	< 0,05		Total impurities: Max 0.2%	< 0,05
PERDITA ALL'ESSICCAMENTO	Max: 0.5%	0,17	LOSS ON DRYING	Max: 0.5%	0,17
CENERI SOLFORICHE	Max 0.1%	< 0.1	SULPHATED ASH	Max 0.1%	< 0.1
TITOLO	99.0% ÷ 101.0% (sostanza essiccata)	100,1	ASSAY	99.0% ÷ 101.0% (dried substance)	100,1

ANALISI PRODOTTO FINITO	SPECIFICHE	RISULTATI	FINISHED PRODUCT ANALYSIS	SPECIFICATIONS	RESULTS
IDENTIFICAZIONE IR	Conforme	Conforme	IR IDENTIFICATION	Conform	Complies
ANALISI MICROBIOLOGICA	TAMC: Max 1000 CFU/g	Conforme	MICROBIOLOGICAL ANALYSIS	TAMC: Max 1000 CFU/g	Complies
	TYMC: Max 100 CFU/g	Conforme		TYMC: Max 100 CFU/g	Complies

ANNOTAZIONI	NOTES
CONSERVAZIONE	Conservare al di sotto di 30°C, escursione termica permessa fino a 40°C.
CERTIFICAZIONE BSE/TSE	Il produttore della materia prima dichiara che il prodotto è privo di contaminazione da BSE/TSE.
	STORAGE
	Store below 30°C, excursions permitted to 40°C.
	BSE/TSE CERTIFICATE
	The manufacturer declares that the product is BSE/TSE contamination free.

FARMALABOR Srl

Sede legale Via Pozzillo Il traversa a sx, 1
76012 Canosa di Puglia (Bt) - Italia

Sede di rappresentanza Via Palermo, 23 - 20057 - Assago (MI) - Italia
CCIAA di Bari - REA n. 432773 - PI05676410722 - Cap. Soc. € 360,000,00 i.v.

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AZIENDA CON
SISTEMI DI GESTIONE QUALITA'
UNI EN ISO 9001:2015
UNI EN ISO 14001:2015
UNI ISO 45001:2018
CERTIFICATA DA CERTIQUALITY
COMPANY WITH CERTIFIED
MANAGEMENT SYSTEMS
UNI EN ISO 9001:2015
UNI EN ISO 14001:2015
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ISSUED BY CERTIQUALITY

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Data di analisi - Analysis date: 20/08/2024

**Produttore Materia Prima
Raw material manufacturer:** COSMA S.p.A. - Italia
Via Colleoni, 15/17 - 24040 Ciserano (BG)

Lotto produttore materia prima - Raw material manufacturer batch number: 202400175/102824005

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Il presente documento è valido senza firma ed è copia conforme del certificato di analisi firmato in originale ed archiviato in Farmalabor nel relativo Batch Record

This document is valid without signature and is a compliant copy of the analysis signed in original and archived in Farmalabor in its Batch Record

Approvato da Persona Qualificata / Approved by Qualify Person

Dott. Alessandro Luisi

Spazio riservato alla Farmacia

DATA RICEZIONE _____

NR. INTERNO: _____

NR DDT/FATTURA : _____

DATA UTILIZZO _____

DATA FINE UTILIZZO : _____

QUANTITA': _____

COSTO: _____

PREZZO AL PUBBLICO : _____

SIGLA RESP.LAB. : _____



COSMA S.p.A.
 Società con socio unico
 Cap. Soc. € 954.600 i.v. - Cod. Fisc. / Part. IVA IT 00714610169
 Via Colleoni, 15/17 - 24040 CISERANO (Bergamo) - ITALY
 telefono 035.88.30.55 - Telefax 035.482.05.01
 PEC: cosmaspa@legalmail.it
 Codice destinatario: SUBM70N

Ciserano, 22/02/2024				
ANALYSIS No. F127/2024		BATCH No. 102824005		
Manufacturing date: 10 January 2024		Retest date: 10 January 2029		Batch size: 1011,00 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 : C ₁₆ H ₂₁ NO ₂ .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	163.4 °C - 164.0 °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	0.02 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.009 %	n.m.t. 0,1%	n.m.t. 0,1%	
ASSAY				
NaOH 0,1N (on dried substance)	100.01 %		min. 99,0% max. 101,0%	
HPLC (on dried substance)	99.57 %	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	0.02 %	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	0.02 %	n.m.t. 0,10%	n.m.t. 0,10%	
Total Impurities	0.07 %	n.m.t. 0,4%	n.m.t. 0,2%	

Qualified Person

N° DI LOTTO ASSEGNATO

Quality Control Manager

202400175-

Ciserano, 22/02/2024		BATCH No. 102824005		
ANALYSIS No. F127/2024				
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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 : C ₁₆ H ₂₁ NO ₂ .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
FOREIGN SUBSTANCES				n.m.t. 15 ppm
<i>Powders</i>	n.m.t. 15 ppm			n.l.t. 50% passes 53 μm
<i>Particle size</i>	89.0 %			mcm
<i>Bulk density</i>	0.30 g/ml			min. 0,25 g/ml max. 0,45 g/ml
<i>Tapped density</i>	0.54 g/ml			min. 0,40 g/ml max. 0,60 g/ml
RESIDUAL SOLVENTS				n.m.t. 500 ppm n.m.t. 300 ppm
<i>Acetone</i>	Not quantifiable			
<i>Toluene</i>	Not detectable			n.m.t. 3,75 ppm
<i>Residual Epichlorohydrin</i>	Non routine test			
<i>Non routine determination</i>				n.m.t. 3,75 ppm
<i>Residual PPEP2</i>	Non routine test			
<i>Non routine determination</i>				
<i>Residual 1-Naphtol and 2-Naphtol</i>				n.m.t. 1000 ppm n.m.t. 1000 ppm
<i>1-Naphtol Content</i>	Non routine test			
<i>2-Naphtol Content</i>	Non routine test			
<i>Non routine determination</i>				



COSMA S.p.A.
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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
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.,

Quality Assurance
 CFM SpA
 08/03/24

Qualified Person

Release date: 06/03/2024

N° DI LOTTO ASSEGNATO
 2024 00175 -

Quality Control Manager