

## CERTIFICATO DI ANALISI - CERTIFICATE OF ANALYSIS

**Prodotto - Product:** 001907\_001 PROPRANOLOLO CLORIDRATO - PROPRANOLOL HYDROCHLORIDE - PROPRANOLOLI HYDROCHLORIDUM

**Conformità - Compliance:** EP

**Lotto - Batch Number:** F2400074

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

**Data produzione - Manufacturing date:** 02/04/2024

**Data scadenza - Expiry date:** 10/01/2029

**Data di analisi - Analysis date:** 04/04/2024

**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

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
<b>PH.EUR.</b>			<b>PH.EUR.</b>		
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.

**Tel** +39 0883 1975 111

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**Web** www.farmalabor.it

AZIENDA CON  
SISTEMI DI GESTIONE QUALITÀ  
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  
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UNI ISO 45001:2018  
ISSUED BY CERTIQUALITY

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**Conformità - Compliance:** EP

**Lotto - Batch Number:** F2400074

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**Data di analisi - Analysis date:** 04/04/2024

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**Raw material manufacturer:** 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.ssa Elisabetta Mancino**

Spazio riservato alla Farmacia

DATA RICEZIONE _____	NR. INTERNO: _____	NR DDT/FATTURA : _____
DATA UTILIZZO _____	DATA FINE UTILIZZO : _____	QUANTITA': _____
COSTO: _____	PREZZO AL PUBBLICO : _____	SIGLA RESP.LAB. : _____

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**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				
<b>ANALYSIS No.</b> F127/2024		<b>BATCH No.</b> 102824005		
Manufacturing date: <b>10 January 2024</b>		Retest date: <b>10 January 2029</b>		Batch size: <b>1011,00 Kg</b>
<b>PRODUCT</b>		<b>PROPRANOLOL HYDROCHLORIDE USP / PH. EUR.</b>		
		<b>CAS N. 318-98-9</b>		
Physical State: crystalline powder		Molecular weight: 295.81		
Colour: white to off-white		Formula : C <sub>16</sub> H <sub>21</sub> NO <sub>2</sub> .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
<b>IDENTIFICATION</b>				
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
<b>Acidity or alkalinity</b>	Conform		Conform	
<b>Clarity and colour of solution</b> (10% in methanol)	Clear n.m.t. brown-yellow degree 6		Clear n.m.t. brown-yellow degree 6	
<b>Loss on drying</b>	0.02 %	n.m.t. 0,5%	n.m.t. 0,5%	
<b>Sulphated ash</b>	0.009 %	n.m.t. 0,1%	n.m.t. 0,1%	
<b>ASSAY</b>				
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%		
<b>Related substances (HPLC)</b>				
<b>Labelled Impurities</b>				
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%	
<b>Unknown Impurity Max</b>	0.02 %	n.m.t. 0,10%	n.m.t. 0,10%	
<b>Total Impurities</b>	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		<b>BATCH No.</b> 102824005		
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Colour:	white to off-white	Formula : C <sub>16</sub> H <sub>21</sub> NO <sub>2</sub> .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
<b>FOREIGN SUBSTANCES</b>				n.m.t. 15 ppm
Powders	n.m.t. 15 ppm			n.l.t. 50% passes 53 mcm
Particle size	89.0 %			min. 0,25 g/ml max. 0,45 g/ml
Bulk density	0.30 g/ml			min. 0,40 g/ml max. 0,60 g/ml
Tapped density	0.54 g/ml			
<b>RESIDUAL SOLVENTS</b>				n.m.t. 500 ppm n.m.t. 300 ppm
Acetone	Not quantifiable			
Toluene	Not detectable			n.m.t. 3,75 ppm
Residual Epichlorohydrin	Non routine test			
Non routine determination				n.m.t. 3,75 ppm
Residual PPEP2	Non routine test			
Non routine determination				
Residual 1-Naphtol and 2-Naphtol				n.m.t. 1000 ppm n.m.t. 1000 ppm
1-Naphtol Content	Non routine test			
2-Naphtol Content	Non routine test			
Non routine determination				



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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