



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212011

Product:	PREDNICARBATE
Lot:	212011
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.4
Synonyms:	
Formula:	C ₂₇ H ₃₆ O ₈
Molecular weight:	488,57 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Specific rotation	+63	(+60) - (+66)	
Loss on drying	0,35 %	<= 0,5 %	
Related substances (HPLC)	Conform		
Assay (HPLC)	100,2 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity B	<= 0,05 %	<= 0,2 %	
Impurity C	0,08 %	<= 0,5 %	
Impurity D	<= 0,05 %	<= 0,2 %	
Impurity E	NDT	<= 0,3 %	
Impurity F	0,14 %	<= 0,8 %	
Impurity G	NDT	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	0,22 %	<= 2,0 %	
Residual solvent: Isopropyl ether	<= 2000 ppm	<= 2000 ppm	#
Residual solvent: Tetrahydrofuran	<= 720 ppm	<= 720 ppm	#
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Methyl isobutyl ketone	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Pyridine	<= 200 ppm	<= 200 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 27/05/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01020 CRYSTAL PHARMA, S.A.U.

Manufacturer batch: C0333-121010

Product	Name	Capacity	Batch
1115239	PREDNICARBATO	0,5 g	212011-C-1
1115239	PREDNICARBATO	0,5 g	212011-C-2
1115239	PREDNICARBATO	0,5 g	212011-C-3
1115239	PREDNICARBATO	0,5 g	212011-C-4
1115240	PREDNICARBATO	1 g	212011-D-1
1115240	PREDNICARBATO	1 g	212011-D-2
1115240	PREDNICARBATO	1 g	212011-D-3
1115240	PREDNICARBATO	1 g	212011-D-4
1115241	PREDNICARBATO	5 g	212011-E-1
1115241	PREDNICARBATO	5 g	212011-E-2
1115241	PREDNICARBATO	5 g	212011-E-3
1115241	PREDNICARBATO	5 g	212011-E-4

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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