

## Prednisolone

<b>CODE ARTICLE:</b> 9219	<b>BATCH:</b> 0114491	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 17/06/2022	<b>TEST:</b> QC-00243865	
<b>EXPIRY DATE:</b> 28/02/2026	<b>FABRICATION DATE:</b> 31/03/2021	<b>MR:</b> 360,40
<b>CAS:</b> [50-24-8]	<b>FORMULA:</b> C <sub>21</sub> H <sub>28</sub> O <sub>5</sub>	
<b>SYNONYMS / BOTANICAL NAME:</b> Cortisol; 1-Dehidrocortisol; 1,2-Dehidrocortisona; 1-Dehidrocortisona; Delta F; Delta-; Dehidrocortisona; Deltahidrocortisona; Esterolona; Glucortín; 1-Hidrocortisona; Hidroretrocortina; Insolona; Intalsolona; Meprisolona; Metacortandralona; Nurisolon; Paracortel; Prenolona		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	WHITE OR ALMOST WHITE, CRYSTALLINE POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
<b><u>SOLUBILITY</u></b>					
SOLUBLE	VERY SLIGHTLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ETHANOL				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
<b><u>IDENTIFICATION</u></b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	113 DEGREES		113	119	PH.EUR.*
<b><u>RELATED SUBSTANCES</u></b>					
TOTAL IMPURITIES	0,5 %			<= 1.5% (<= 15xa ref c)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL (0,05%) (PASS) %			<= 0.10% (<= A ref c)	PH.EUR.*
IMPURITY A	0,4% (PASS) %			<= 1.0% (<= 10xa ref c)	PH.EUR.*
IMPURITY B	0,1% (PASS) %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
IMPURITY C	<DL (0,05%) (PASS) %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
IMPURITY F	<DL (0,05%) (PASS) %			<= 0.5% (<= 5xa ref c)	PH.EUR.*
IMPURITY J	<DL (0,05%) (PASS) %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,66 %		96,5	102	PH.EUR.*
<b><u>RESIDUAL SOLVENTS</u></b>					
METHANOL	N.D. ppm			700	Manufacture's Standard
CLORURO DE METILO	85 ppm		0,0	600	Manufacture's Standard
ORIGIN PACKAGING MATERIAL	NATURAL PELD				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 10				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 405601 H. L. PHARMACEUTICAL CO.,LTD. (China) Manufacturer Batch: K04120210402 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



**Prednisolone**

<b>CODE ARTICLE:</b> 9219	<b>BATCH:</b> 0114491	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 17/06/2022	<b>TEST:</b> QC-00243865	
<b>EXPIRY DATE:</b> 28/02/2026	<b>FABRICATION DATE:</b> 31/03/2021	<b>MR:</b> 360,40
<b>CAS:</b> [50-24-8]	<b>FORMULA:</b> C21H28O5	
<b>SYNONYMS / BOTANICAL NAME:</b> Cortisai; 1-Dehidrocortisol; 1,2-Dehidrocortisona; 1-Dehidrocortisona; Delta F; Delta-; Dehidrocortisona; Deltahidrocortisona; Esterolona; Glucortín; 1-Hidrocortisona; Hidroretrocortina; Insolona; Intalsolona; Meprisolona; Metacortandralona; Nurisolon; Paracortel; Prenolona		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				



**Silvia Sancho-Tello Ripoll**  
Technical Director.

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 405601 H. L. PHARMACEUTICAL CO.,LTD. (China) Manufacturer Batch: K04120210402 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

