

## Prednisolone

<b>CODE ARTICLE:</b> 11131	<b>BATCH:</b> 0119871	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 14/06/2023	<b>TEST:</b> QC-00254241	
<b>EXPIRY DATE:</b> 28/02/2028	<b>FABRICATION DATE:</b> 22/03/2023	<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>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		Dust	PH.EUR.*
COLOUR	CONFORM	-		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	115 DEGREES		113	119	PH.EUR.*
<b><u>RELATED SUBSTANCES</u></b>					
TOTAL IMPURITIES	0,6% (CONFORME) %			<= 1.5% (<= 15xa ref c)	PH.EUR.*
UNSPECIFIED IMPURITIES	< DL=0,05% (PASS) %			<= 0.10% (<= A ref c)	PH.EUR.*
IMPURITY A	0,6% (CONFORME) %			<= 1.0% (<= 10xa ref c)	PH.EUR.*
IMPURITY B	< DL=0,05% (PASS) %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
IMPURITY C	N.D. %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
IMPURITY F	N.D. %			<= 0.5% (<= 5xa ref c)	PH.EUR.*
IMPURITY J	< DL=0,05% (PASS) %			<= 0.3% (<= 3xa ref c)	PH.EUR.*
LOSS ON DRYING	0,3 %		0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	97,1 %		96,5	102	PH.EUR.*
<b><u>RESIDUAL SOLVENTS</u></b>					
METHANOL	N.D. ppm			700	Manufacture's Standard
CLORURO DE METILO	41 ppm		0,0	600	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

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: K04120230316 Manufacturer original CoA available under request

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<b>CAS:</b> [50-24-8]	<b>FORMULA:</b> C21H28O5	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
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*This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.*



**Este producto ha sido manipulado en sala NO estéril, para lotes aptos uso estéril consultar disponibilidad.**

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

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