

Prednisolone

CODE ARTICLE: 11131	BATCH: 0122740	Active pharmaceutical ingredient
TEST DATE: 25/10/2023	TEST: QC-00257954	
EXPIRY DATE: 30/07/2028	FABRICATION DATE: 14/08/2023	MR: 360,40
CAS: [50-24-8]	FORMULA: C21H28O5	
STORAGE: 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.*
<u>SOLUBILITY</u>					
SOLUBLE	VERY SLIGHTLY SOLUBLE IN				PH.EUR.*
	WATER				
SOLUBLE	ETHANOL				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN				PH.EUR.*
	ACETONE				
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	117 DEGREES		113	119	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	0,3%(PASS) %			<= 1.5% (<= 15xa ref c)	PH.EUR.*
UNSPECIFIED IMPURITIES	< DL=0,05% (PASS) %			<= 0.10% (<= A ref c)	PH.EUR.*
IMPURITY A	0,3%(PASS) %			<= 1.0% (<= 10xa ref c)	PH.EUR.*
IMPURITY B	< DL=0,05% (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)	97,4 %		96,5	102	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	44 ppm			700	Manufacturer's Standard
CLORURO DE METILO	136 ppm		0,0	600	Manufacturer's Standard
SAMPLING	COLLECT				Manufacturer's Standard
CORRECT BATCH	YES				Manufacturer's Standard
SPECIFICATION	PH.EUR 11				Manufacturer's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

NON-sterile

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: K04120230819 Manufacturer original CoA available under request

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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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