

Prednisolone

CODE ARTICLE: 93693	BATCH: 0098855	Active pharmaceutical ingredient
TEST DATE: 26/11/2020	TEST: QC-00226692	
EXPIRY DATE: 30/06/2025	MR: 360,40	
CAS: [50-24-8]	FORMULA: C21H28O5	
SYNONYMS / BOTANICAL NAME: Cortisal; 1-Dehidrocortisol; 1,2-Dehidrocortisona; 1-Dehidrocortisona; Delta F; Delta-; Dehidrocortisona; Deltahidrocortisona; Esterolona; Glucortín; 1-Hidrocortisona; Hidroretrocortina; Insolona; Intalsolona; Meprisolona; Metacortandralona; Nurisolon; Paracortel; Prenolona		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	WHITE CRYSTAL POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	VERY SLIGHTLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ETHANOL				PH.EUR.*
SOLUBLE	VERY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	115 DEGREES		113	119	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	<1,5 %			1,5	PH.EUR.*
UNSPECIFIED IMPURITIES	<0,10 %			0,10	PH.EUR.*
IMPURITY A	<1,0 %			1,0	PH.EUR.*
IMPURITY B	<0,3 %			0,30	PH.EUR.*
IMPURITY C	<0,3 %			0,30	PH.EUR.*
IMPURITY F	<0,5 %			0,50	PH.EUR.*
IMPURITY J	<0,3 %			0,30	PH.EUR.*
LOSS ON DRYING	0,02 %		0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	97,82 %		96,5	102	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	25 ppm		0,0	700	Manufacture's Standard
CLORURO DE METILO	103 ppm		0,0	600	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 10.0				Manufacture's Standard



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: K04I20200706 Manufacturer original CoA available under request

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