GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Prednisolone

CODE ARTICLE: 11131	**BATCH:** 0131097 **Active pharmaceutical ingredient**
TEST DATE: 25/09/2024	**TEST:** QC-00268352
EXPIRY DATE: 30/06/2029 **FABRICATION DATE:** 20/07/2024	**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	PASS	-		POWDER	PH.EUR.*
COLOUR	PASS	-		WHITE	PH.EUR.*
SOLUBILITY					
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.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
IDENTIFICATION (HPLC)	PASS				PH.EUR.*
SPECIFIC ROTATION	115	DEGREES	113	119	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,5% (PASS)	%		<=1,5% (<=15xA Ref c)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,05% (PASS)	%		<=0,10% (<=A Ref c)	PH.EUR.*
IMPURITY A	0,5% (PASS)	%		<=1,0% (<=10xA Ref c)	PH.EUR.*
IMPURITY B	<DL=0,05% (CONFORM)	%		<=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	0,1	%	0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	97,2	%	96,5	102	PH.EUR.*
PARTICLE SIZE <30 MICRAS	98	%			Manufacture's Standard
PARTICLE SIZE <15 MICRAS	80	%			Manufacture's Standard
RESIDUAL SOLVENTS					
METHANOL	25	ppm	0,0	700	Manufacture's Standard
CLORURO DE METILO	110	ppm	0,0	600	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				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: K04120240722 Manufacturer original CoA available under request

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GOOD MANUFACTURING PRACTICE GMP

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TEST	RESULTS	Units	MIN	MAX	METHOD
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				

NON-sterile

The product has been handled in NON-sterile rooms, so this product is NOT STERILE.

Silvia Sancho-Tello Ripoll
Technical Director.

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