GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Hydrocortisone acetate

CODE ARTICLE: 90994	**BATCH:** 0118993 **Active pharmaceutical ingredient**
TEST DATE: 04/05/2023	**TEST:** QC-00252913
EXPIRY DATE: 30/01/2028 **FABRICATION DATE:** 01/02/2023	**MR:** 404,50
CAS: [50-03-3]	**FORMULA:** C23H32O6
SYNONYMS / BOTANICAL NAME: Acetato de cortisol; 21-Acetato de hidrocortisona; Acetilhidrocortisona; Hidrocortisona acetilada	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			POLVO CRISTALINO	PH.EUR.*
COLOUR	CONFORM			White	PH.EUR.*
SOLUBILITY					
SOLUBLE	SLIGHTLY SOLUBLE IN ANHIDROUS ETHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	165	DEGREES	158	167	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,3%(PASS)	-		<= 1.5% (<15xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,05% (PASS)	-		<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY A	0,1% (PASS)	-		<= 0.5% (<5xArea RS b)	PH.EUR.*
IMPURITY B	< DL=0,05% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY C	0,1% (PASS)	-		<= 0.6% (<6xArea RS b)	PH.EUR.*
IMPURITY D	< DL=0,05% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY E	< DL=0,05% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY G	N.D.	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
LOSS ON DRYING	0,1	%	-	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	98	%	97	102	PH.EUR.*
RESIDUAL SOLVENTS					
ACETONE	407	ppm	-	5.000	Manufacture's Standard
METHANOL	N.D.	ppm		<=3000	Manufacture's Standard
DICHLOROMETHANE	N.D.	MG/KG		<=600	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: K06M20230302M Manufacturer original CoA available under request

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GOOD MANUFACTURING PRACTICE GMP

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

This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.

This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.

Silvia Sancho-Tello Ripoll
Technical Director.

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