GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Hydrocortisone acetate

CODE ARTICLE: 97646	**BATCH:** 0102701 **Active pharmaceutical ingredient**
TEST DATE: 29/04/2021	**TEST:** QC-00231636
EXPIRY DATE: 30/04/2025	**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	WHITE OR ALMOST WHITE, CRYSTALLINE POWDER				PH.EUR.*
COLOUR	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	160	DEGREES	158	167	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,36%(PASS)	-		<= 1.5% (<15xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,06% (PASS)	-		<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY A	0,16% (PASS)	-		<= 0.5% (<5xArea RS b)	PH.EUR.*
IMPURITY B	0,08% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY C	<LQ=0,05% (PASS)	-		<= 0.6% (<6xArea RS b)	PH.EUR.*
IMPURITY D	<LQ=0,05% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY E	<LQ=0,05% (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY G	<LQ=0,05% (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
LOSS ON DRYING	0,1	%	-	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,9	%	97	102	PH.EUR.*
RESIDUAL SOLVENTS					
DICHLOROMETHANE	N.D.	ppm		<=600	Manufacture's Standard
ACETONE	642	ppm	-	5.000	Manufacture's Standard
METHANOL	N.D.	ppm		<=3000	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: K06M20200605 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 10.0				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

Silvia Sancho-Tello Ripoll
Technical Director.

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