

## Hydrocortisone acetate

<b>CODE ARTICLE:</b> 90994	<b>BATCH:</b> 0128225	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 16/04/2024	<b>TEST:</b> QC-00263355	
<b>EXPIRY DATE:</b> 30/12/2028	<b>FABRICATION DATE:</b> 18/01/2024	<b>MR:</b> 404,50
<b>CAS:</b> [50-03-3]	<b>FORMULA:</b> C23H32O6	
<b>SYNONYMS / BOTANICAL NAME:</b> Acetato de cortisol; 21-Acetato de hidrocortisona; Acetilhidrocortisona; Hidrocortisona acetilada		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS			CRYSTALLINE POWDER	PH.EUR.*
COLOUR	PASS			White	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	SLIGHTLY SOLUBLE IN ANHIDROUS ETHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	PASS				PH.EUR.*
IDENTIFICATION (HPLC)	PASS				PH.EUR.*
SPECIFIC ROTATION	160 DEGREES		158	167	PH.EUR.*
<b>RELATED SUBSTANCES</b>					
TOTAL IMPURITIES	0,2% (CONFORME) -			<= 1.5% (<15xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	< DL=0,05% (PASS) -			<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY A	0,1% (CONFORME) -			<= 0.5% (<5xArea RS b)	PH.EUR.*
IMPURITY B	N.D. -			<= 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	0,1% (CONFORME) -			<= 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)	98,2 %		97	102	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
ACETONE	384 ppm		-	5.000	Manufacture's Standard
METHANOL	24 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: K06M20240107 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



**Hydrocortisone acetate**

<b>CODE ARTICLE:</b> 90994	<b>BATCH:</b> 0128225	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 16/04/2024	<b>TEST:</b> QC-00263355	
<b>EXPIRY DATE:</b> 30/12/2028	<b>FABRICATION DATE:</b> 18/01/2024	<b>MR:</b> 404,50
<b>CAS:</b> [50-03-3]	<b>FORMULA:</b> C23H32O6	
<b>SYNONYMS / BOTANICAL NAME:</b> Acetato de cortisol; 21-Acetato de hidrocortisona; Acetilhidrocortisona; Hidrocortisona acetilada		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				
<i>NON-sterile</i>					



**The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE**

**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: K06M20240107 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

