

Triamcinolone acetoneide

CODE ARTICLE: 93494	BATCH: 0133672	Active pharmaceutical ingredient
TEST DATE: 16/12/2024	TEST: QC-00270971	
EXPIRY DATE: 30/05/2027	FABRICATION DATE: 01/06/2024	MR: 434,50
CAS: [76-25-5]	FORMULA: C24H31FO6	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			CRYSTAL POWDER	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	MODERATELY SOLUBLE IN				PH.EUR.*
	ETHANOL 96				
INSOLUBLE	PRACTICALLY INSOLUBLE IN				PH.EUR.*
	WATER				
<u>IDENTIFICATION</u>					
IDENTIFICATION A (IR SPECTRUM)	PASS				PH.EUR.*
IDENTIFICATION B (TLC)	PASS				PH.EUR.
IDENTIFICACION C (HPLC)	PASS				PH.EUR.*
IDENTIFICATION D	PASS				PH.EUR.
OPTICAL ROTATION (ANHYDROUS SUBSTANCE)	112 -		110	117	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	<0,5% -			<=0,5% (<= 5xArea Triamcinolona RS B)	PH.EUR.*
UNSPECIFIED IMPURITIES	<0,10% -			<=0,10% (<=A Triam.RS B)	PH.EUR.*
IMPURITY B	<0,2% -			<=0,2% (<=2xA Triam.RS B)	PH.EUR.*
IMPURITY C	<0,15% -			<=0,15% (<=1,5 xA Triam.RS B)	PH.EUR.*
WATER	1,3 %		0,0	2	PH.EUR.*
ASSAY (ANHIDROUS BASIS)	98,6 %		97,5	102	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
ACETONE	128 ppm		0,0	1.000	Manufacture's Standard
METHANOL	324 ppm		0,0	1.000	Manufacture's Standard
DICHLOROMETHANE	13 ppm		0,0	150	Manufacture's Standard
BENZENE	N.D. ppm			2	Manufacture's Standard
PARTICLE SIZE	7,37 MICRONS			D(09)<=10 micras	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				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: 57131 C. D. PVT LTD (India) Manufacturer Batch: 6702024013 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

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TEST	RESULTS	Units	MIN	MAX	METHOD
Elemental Impurities ICHQ3D	PASS				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				Manufacture's Standard

NON-sterile



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

Silvia Sancho-Tello Ripoll
Technical Director.

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