

## Triamcinolone acetoneide

<b>CODE ARTICLE:</b> 93493	<b>BATCH:</b> 0129077	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 25/06/2024	<b>TEST:</b> QC-00265669	
<b>EXPIRY DATE:</b> 30/03/2027	<b>FABRICATION DATE:</b> 01/04/2024	<b>MR:</b> 434,50
<b>CAS:</b> [76-25-5]	<b>FORMULA:</b> C <sub>24</sub> H <sub>31</sub> FO <sub>6</sub>	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS	-		POLVO CRISTAL	PH.EUR.*
COLOUR	PASS	-		BLANCO	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	MODERATELY SOLUBLE IN ETHANOL 96				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
<b>IDENTIFICATION</b>					
IDENTIFICATION A (IR SPECTRUM)	PASS				PH.EUR.*
IDENTIFICATION B (TLC)	PASS				PH.EUR.
IDENTIFICACION C (HPLC)	PASS				PH.EUR.*
IDENTIFICATION D	PASS				PH.EUR.
ROTACION OPTICA (SUST. ANHIDRA)	116	-	110	117	PH.EUR.*
<b>RELATED SUBSTANCES</b>					
TOTAL IMPURITIES	0,2% (CONFORME)	-		<=0,5% (<=5xArea Triamcinolona RS B)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,09% (PASS)	-		<=0,10% (<=A Triam.RS B)	PH.EUR.*
IMPURITY B	0,1% (CONFORME)	-		<=0,2% (<=2xA Triam.RS B)	PH.EUR.*
IMPURITY C	<LQ=0,05% (PASS)	-		<=0,15% (<=1,5 xA Triam.RS B)	PH.EUR.*
WATER	1,3	%	0,0	2	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	99	%	97,5	102	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
ACETONE	76	ppm	0,0	1.000	Manufacturer's Standard
METHANOL	269	ppm	0,0	1.000	Manufacturer's Standard
DICHLOROMETHANE	12	ppm	0,0	150	Manufacturer's Standard
BENZENE	N.D.	ppm		2	Manufacturer's Standard
PARTICLE SIZE <10 MICRON	6,29	%	99		Manufacturer's Standard
CORRECT BATCH	YES				Manufacturer's Standard
SAMPLING	COLLECT				Manufacturer's Standard
SPECIFICATION	PH.EUR 11				Manufacturer'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: 6702024008 Manufacturer original CoA available under request

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<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

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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