GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Triamcinolone acetonide

CODE ARTICLE: 93494	**BATCH:** 0120471 **Active pharmaceutical ingredient**
TEST DATE: 07/07/2023	**TEST:** QC-00255058
EXPIRY DATE: 30/01/2028 **FABRICATION DATE:** 28/02/2023	**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	CONFORM	-		Crystal dust	PH.EUR.*
COLOUR	CONFORM	-		White	PH.EUR.*
SOLUBILITY					
SOLUBLE	SPARINGLY SOLUBLE IN ETHANOL				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION C	CONFORM				PH.EUR.*
ROTACION OPTICA (SUST. ANHIDRA)	111	-	110	117	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,3%(PASS)	-		<= 0.5% (<= 5xarea Triamcinolone RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	< DL=0,05% (PASS)	-		<= 0.10% (<= Triamcinolone Area RS B)	PH.EUR.*
IMPURITY B	0,2% (CONFORME)	-		<= 0.2% (<= 2xarea triamcinolone RS b)	PH.EUR.*
IMPURITY C	0,14% (PASS)	-		<= 0.15% (<= 1.5xarea triamcinolone RS b)	PH.EUR.*
WATER	0,6	%	0,0	2	PH.EUR.*
ASSAY (ANHIDROUS BASIS)	99,6	%	97,5	102	PH.EUR.*
RESIDUAL SOLVENTS					
ACETONE	679	ppm	0,0	5.000	Manufacture's Standard
METHANOL	252	ppm	0,0	3.000	Manufacture's Standard
DICHLOROMETHANE	118	ppm	0,0	600	Manufacture's Standard
ACETIC ACID	N.D.	mg/kg		5000	Manufacture's Standard
DIISOPROPYLETHER	N.D.	mg/kg		5000	Manufacture's Standard
PARTICLE SIZE <10 MICRON	CONFORM	%	99		Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				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: 53686 M. P. C. PVT. LTD. (India) Manufacturer Batch: TRAFP23001 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

GOOD MANUFACTURING PRACTICE GMP

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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

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

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Silvia Sancho-Tello Ripoll
Technical Director.

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