GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Triamcinolone acetonide

CODE ARTICLE: 93493	**BATCH:** 0119322 **Active pharmaceutical ingredient**
TEST DATE: 23/05/2023	**TEST:** QC-00253516
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 Powder	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

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

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GOOD MANUFACTURING PRACTICE GMP

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TEST	RESULTS	Units	MIN	MAX	METHOD
SPECIFICATION	PH.EUR 11				Manufacture's Standard
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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