GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Dexamethasone

CODE ARTICLE: 94154	**BATCH:** 0129292 **Active pharmaceutical ingredient**
TEST DATE: 15/07/2024	**TEST:** QC-00266421
EXPIRY DATE: 18/01/2028 **FABRICATION DATE:** 18/01/2024	**MR:** 392,50
CAS: [50-02-2]	**FORMULA:** C22H29FO5
SYNONYMS / BOTANICAL NAME: Hexadecadrol	
STORAGE: 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.*
SOLUBILITY					
SOLUBLE	SPARINGLY SOLUBLE IN ABSOLUT ETHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
TLC	PASS				PH.EUR.*
SPECIFIC ROTATION	90	DEGREES	86	92	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,09% (PASS)	-		<= 0.5% (<5xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL=0,05% (CONFORM)	-		<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY G	<DL=0,05% (CONFORM)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY B	<DL=0,05% (CONFORM)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY F	<DL=0,05% (CONFORM)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY J	0,09% (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY K	<DL=0,05% (CONFORM)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
LOSS ON DRYING	0,1	%	0,0	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,4	%	97	103	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	138	ppm	-	3.000	Manufacture's Standard
CHLOROFORM	N.D.	MG/KG		60	Manufacture's Standard
N,N-DIMETHYL FORMAMIDE	N.D.	ppm	-	880	Manufacture's Standard
PARTICLE SIZE	PASS			99% <30um	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: 409865 T. T. PHARMACEUTICAL, CO., LTD. (China) Manufacturer Batch: NUD240201 Manufacturer original CoA available under request

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GOOD MANUFACTURING PRACTICE GMP

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TEST	RESULTS	Units	MIN	MAX	METHOD
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				PH.EUR.
Elemental Impurities ICHQ3D	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				

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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