

Dexamethasone

CODE ARTICLE: 94155	BATCH: 0132933	Active pharmaceutical ingredient
TEST DATE: 27/12/2024	TEST: QC-00271146	
EXPIRY DATE: 30/08/2028	FABRICATION DATE: 11/09/2024	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.*
<u>SOLUBILITY</u>					
SOLUBLE	SPARINGLY SOLUBLE IN ABSOLUT ETHANOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	PASS				PH.EUR.*
TLC	PASS				PH.EUR.*
SPECIFIC ROTATION	90 DEGREES		86	92	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	<0,5% -			<= 0.5% (<5xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	<0,10% -			<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY G	<0,3% -			<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY B	<0,15% -			<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY F	<0,15% -			<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY J	<0,15% -			<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY K	<0,15% -			<= 0.15% (<1.5xarea rs b)	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	98,5 %		97	103	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	158 ppm		-	3.000	Manufacture's Standard
CHLOROFORM	N.D. ppm			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: NUD240902 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



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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				
<i>NON-sterile</i>					



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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