

Dexamethasone

CODE ARTICLE: 94154	BATCH: 0121252	Active pharmaceutical ingredient
TEST DATE: 27/07/2023	TEST: QC-00255718	
EXPIRY DATE: 30/03/2027	FABRICATION DATE: 01/04/2023	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	CONFORM	-		POLVO CRISTAL	PH.EUR.*
COLOUR	PASS	-		BLANCO	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	CONFORM				PH.EUR.*
TLC	CONFORM				PH.EUR.*
SPECIFIC ROTATION	90 DEGREES		86	92	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	0,1% (PASS)	-		<= 0.5% (<5xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,07% (PASS)	-		<= 0.10% (<area RS b)	PH.EUR.*
IMPURITY G	<DL (0,05%) (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY B	<DL (0,05%) (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY F	N.D.	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY J	<DL (0,05%) (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY K	<DL (0,05%) (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,9 %		97	103	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	211 ppm		-	3.000	Manufacture's Standard
DICHLOROMETHANE	107 ppm		-	600	Manufacture's Standard
ACETONE	86 MG/KG			5000	Manufacture's Standard
N,N-DIMETHYL FORMAMIDE	N.D. ppm		-	880	Manufacture's Standard
DI ISOPROPYL ETHER	N.D. MG/KG		-	5000	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: DXMFE23002 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

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SYNONYMS / BOTANICAL NAME: Hexadecadrol		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
PARTICLE SIZE	CONFORM			99% <30um	Manufacture's Standard
ORIGIN PACKAGING MATERIAL	NATURAL PELD				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				PH.EUR.
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				

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



Silvia Sancho-Tello Ripoll
Technical Director.

This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.

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