

Betamethasone dipropionate

CODE ARTICLE: 93181	BATCH: 0120181	Active pharmaceutical ingredient
TEST DATE: 26/06/2023	TEST: QC-00254654	
EXPIRY DATE: 28/02/2028	FABRICATION DATE: 30/03/2023	MR: 504,60
CAS: [5593-20-4]	FORMULA: C28H37FO7	
SYNONYMS / BOTANICAL NAME: 17,21-dipropionato de betametasona; 17,21-dipropionato de betametasona; 17,21-; dipropionato de flubenisolona		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POWDER	PH.EUR.*
COLOUR	CONFORM	-		WHITE	PH.EUR.*
SOLUBILITY					
SOLUBLE	SPARINGLY SOLUBLE IN ETHANOL				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
SPECIFIC ROTATION	85 DEGREES		84	88	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	0,4% (PASS)	-		<= 1.0% (<10xArea RS b)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL (0,05%) (PASS)	-		<=0,1% (<Área SR B)	PH.EUR.*
IMPURITY I	<DL (0,05%) (PASS)	-		<= 0.15% (<1.5xarea rs b)	PH.EUR.*
IMPURITY B	<DL (0,05%) (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
IMPURITY C	0,3%(PASS)	-		<= 0.5% (<5xArea RS b)	PH.EUR.*
IMPURITY D	<DL (0,05%) (PASS)	-		<= 0.2% (<2x RS area b)	PH.EUR.*
IMPURITY E	<DL (0,05%) (PASS)	-		<= 0.2% (<2x RS area b)	PH.EUR.*
IMPURITY G	0,1% (PASS)	-		<= 0.2% (<2x RS area b)	PH.EUR.*
IMPURITY H	<DL (0,05%) (PASS)	-		<= 0.3% (<3xArea RS b)	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,6 %		97	102	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	390,18 ppm			3000	Manufacturer's Standard
METHYLENE CHLORIDE	N.D. ppm			600	Manufacturer's Standard
ACETONE	414,54 ppm			5000	Manufacturer's Standard

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TEST	RESULTS	Units	MIN	MAX	METHOD
ETHYL ACETATE	N.D.	ppm		5000	Manufacture's Standard
DIMETHYL SULFOXIDE	N.D.	ppm		880	Manufacture's Standard
PYRIDINE	N.D.	ppm		200	Manufacture's Standard
<i>PARTICLE SIZE</i>					
PARTICLE SIZE <20 MICRON	CONFORM	MICRONS		100%	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				



Silvia Sancho-Tello Ripoll
Technical Director.

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