

## Betamethasone dipropionate

<b>CODE ARTICLE:</b> 96413	<b>BATCH:</b> 0128126	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 31/05/2024	<b>TEST:</b> QC-00264893	
<b>EXPIRY DATE:</b> 30/03/2029	<b>FABRICATION DATE:</b> 01/04/2024	<b>MR:</b> 504,60
<b>CAS:</b> [5593-20-4]	<b>FORMULA:</b> C28H37FO7	
<b>SYNONYMS / BOTANICAL NAME:</b> 17,21-dipropionato de betametasona; 17,21-dipropionato de betametasona; 17,21-; dipropionato de flubenisolona		
<b>STORAGE:</b> 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.*
<b>SOLUBILITY</b>					
SOLUBLE	MODERATELY SOLUBLE IN ETHANOL 96				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	PASS				PH.EUR.*
SPECIFIC ROTATION	85 DEGREES		84	88	PH.EUR.*
<b>RELATED SUBSTANCES (HPLC)</b>					
TOTAL IMPURITIES	0,5% (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	0,4% (PASS) -			<= 0.5% (<5xArea RS b)	PH.EUR.*
IMPURITY D	<DL (0,05%) (PASS) -			<= 0.2% (<2x RS area b)	PH.EUR.*
IMPURITY E	N.D. -			<= 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	0,2 %		0,0	1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	98,1 %		97	102	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
METHANOL	N.D. ppm			3000	Manufacture's Standard
METHYLENE CHLORIDE	N.D. ppm			600	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: 54540 G. P. E. PVT. LTD. (India) Manufacturer Batch: APL/BDP/06016/D-24 Manufacturer original CoA available under request

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ACETONE	664,53	ppm		5000	Manufacture's Standard
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
<b>PARTICLE SIZE</b>					
PARTICLE SIZE <20 MICRON	PASS	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	PASS				
Elemental Impurities ICHQ3D	PASS				



**Silvia Sancho-Tello Ripoll**  
Technical Director.

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