

## Betamethasone valerate

<b>CODE ARTICLE:</b> 98084	<b>BATCH:</b> 0120796	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 17/07/2023	<b>TEST:</b> QC-00255353	
<b>EXPIRY DATE:</b> 15/12/2026	<b>FABRICATION DATE:</b> 15/12/2021	<b>MR:</b> 476,60
<b>CAS:</b> [2152-44-5]	<b>FORMULA:</b> C27H37FO6	
<b>SYNONYMS / BOTANICAL NAME:</b> 17-valerato de betametasona; 17--valerato de betametasona; Valerato de flubenisolona		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			POLVO	PH.EUR.*
COLOUR	CONFORM			BLANCO	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE		ETHANOL 96°			PH.EUR.*
SOLUBLE		FREELY SOLUBLE IN ACETONE			PH.EUR.*
SOLUBLE		FFREELY SOLUBLE IN METHYLENE CHLORIDE			PH.EUR.*
INSOLUBLE		WATER			PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
IDENTIFICACION RAMAN	CONFORM -				Manufacture's Standard*
LOSS ON DRYING		0,2 %	0,0	0,5	PH.EUR.*
RESIDUE ON IGNITION	NEGLIGIBLE			<=0,2	Manufacture's Standard
WATER		0,06 %	0,0	0,5	Manufacture's Standard
ROTAC ESPECIF DIOXANO		77,4 DEGREES	75	82	Manufacture's Standard
SPECIFIC ROTATION		79 DEGREES	77	83	PH.EUR.*
<b>RELATED SUBSTANCES (HPLC)</b>					
IMPURITY A		0,0 %		0,7	PH.EUR.*
IMPURITY I		<0,05 %		0,15	PH.EUR.*
IMPURITY H		<0,05 %		0,15	PH.EUR.*
IMPURITY C		<0,05 %		0,15	PH.EUR.*
IMPURITY G		0,0 %		0,3	PH.EUR.*
IMPURITY E		0 %	0,0	0,3	PH.EUR.*
TOTAL IMPURITIES		0 %	0,0	1,5	PH.EUR.*
UNSPECIFIED IMPURITIES		<0,05 %		0,1	PH.EUR.*
ASSAY (HPLC)		100,3 %	97	103	Manufacture's Standard
ASSAY (SPECTROPHOTOMETRY)		98,6 %	97	103	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
METHANOL		N.D. ppm		200	Manufacture's Standard
ACETONE		1495 ppm	0,0	3.000	Manufacture's Standard
TETRAHYDROFURAN		N.D. ppm		100	Manufacture's Standard
PYRIDINE		N.D. ppm		50	Manufacture's Standard
<b>PARTICLE SIZE</b>					
PARTICLE SIZE <10 MICRON		100,0 %	90,0		Manufacture's Standard
PARTICLE SIZE <20 MICRON		100,0 %	99,0		Manufacture's Standard
PARTICLE SIZE <5 MICRAS		94,2 %	80,0		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.



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

*NON-sterile*



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

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

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Manufacturer: 43264 F. S.P.A. (Italia) Manufacturer Batch: 2109VM0 0012222 Manufacturer original CoA available under request  
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