

## Fluocinolone acetonide

<b>CODE ARTICLE:</b> 93950	<b>BATCH:</b> 0125888	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 01/03/2024	<b>TEST:</b> QC-00261952	
<b>EXPIRY DATE:</b> 13/10/2028	<b>FABRICATION DATE:</b> 13/10/2023	<b>MR:</b> 452,50
<b>CAS:</b> [67-73-2]	<b>FORMULA:</b> C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub>	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		White or almost white crystal powder	PH.EUR.*
COLOUR	CONFORM	-		White	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	ANHIDROUS ETHANOL				PH.EUR.
SOLUBLE	IN ACETONE				PH.EUR.
INSOLUBLE	WATER				PH.EUR.
INSOLUBLE	HEPTANO				PH.EUR.
SOLUBLE	METHANOL				Manufacture's Standard
SOLUBLE	SLIGHTLY SOLUBLE IN CHLOROFORM				Manufacture's Standard
SOLUBLE	SLIGHTLY SOLUBLE IN ETHER				Manufacture's Standard
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	103,5 DEGREES		100	104	PH.EUR.
SPECIFIC ROTATION	103,3 DEGREES		98	108	USP
<b>RELATED SUBSTANCES (HPLC)</b>					
TOTAL IMPURITIES	0,18 %			<=0,7	PH.EUR.
UNSPECIFIED IMPURITIES	<0,05 %			<=0,10	PH.EUR.
IMPURITY A	N.D. %			<=0,10	PH.EUR.
IMPURITY B	<0,05 %			<=0,10	PH.EUR.
IMPURITY C	N.D. %			<=0,10	PH.EUR.
IMPURITY D	0,06 %			<=0,2	PH.EUR.
IMPURITY E	N.D. %			<=0,10	PH.EUR.
IMPURITY H	<0,05 %			<=0,15	PH.EUR.
IMPURITY I	0,12 %			<=0,15	PH.EUR.
IMPURITY M	<0,05 %			<=0,10	PH.EUR.
IMPURITY G	N.D. %			<=0,10	PH.EUR.
LOSS ON DRYING	0,2 %			<=1,0	PH.EUR.*
ASSAY (HPLC) (DRY BASIS).	99,7 %		97,5	102	PH.EUR.*
ASSAY (SPECTROPHOTOMETRY)	100,5 %		97	102	Manufacture's Standard
<b>RESIDUAL SOLVENTS</b>					
METHANOL	N.D. ppm			<=500	Manufacture's Standard
ACETONE	43 ppm			<=1000	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.



**Fluocinolone acetonide**

<b>CODE ARTICLE:</b> 93950	<b>BATCH:</b> 0125888	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 01/03/2024	<b>TEST:</b> QC-00261952	
<b>EXPIRY DATE:</b> 13/10/2028	<b>FABRICATION DATE:</b> 13/10/2023	<b>MR:</b> 452,50
<b>CAS:</b> [67-73-2]	<b>FORMULA:</b> C24H30F2O6	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
METHYLENE CHLORIDE		N.D. ppm		<=500	Manufacture's Standard
<b><i>PARTICLE SIZE</i></b>					
PARTICLE SIZE <30 MICRAS	100,0 %		>=99,0		Manufacture's Standard
PARTICLE SIZE <15 MICRAS	100,0 %		>=95,0		Manufacture's Standard
PARTICLE SIZE <5 MICRAS	87,7 %		>=75,0		Manufacture's Standard
ABSORBANCE AT 238nm	356,8 -		344	366	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11, USP				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

*NON-sterile*



**The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE**

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

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.

