

Tretinoin

CODE ARTICLE: 98122	BATCH: 0126918	Active pharmaceutical ingredient
TEST DATE: 03/04/2024	TEST: QC-00262948	
EXPIRY DATE: 19/01/2027	FABRICATION DATE: 20/01/2024	MR: 300,42
CAS: [302-79-4]	FORMULA: C ₂₀ H ₂₈ O ₂	
SYNONYMS / BOTANICAL NAME: Tretinoína; Ácido trans-retinoico; Tretimoíno; Vitamina A ácida		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	YELLOW OR LIGHT ORANGE, CRYSTALLINE POWDER				PH.EUR.*
COLOUR	YELLOW OR LIGHT-ORANGE				PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN METILENE CHLORIDE				PH.EUR.*
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
MELTING POINT	182 °C		180	184	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	0,1 %			<=1,0	PH.EUR.*
UNSPECIFIED IMPURITIES	0,1 -			<=0,2	PH.EUR.*
ISOTRETINOIN	N.D. -			<=0,5	PH.EUR.*
LOSS ON DRYING	0,1 %			<=0,5	PH.EUR.*
SULPHATED ASHES	0,04 %			<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,9 %		98,0	102,0	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
ETHYL ACETATE	611 ppm			<=5000	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
TOTAL AEROBICS	<20 UFC/G			<=100	Manufacture's Standard
MOLDS AND YEASTS	<20 UFC/G			<=100	Manufacture's Standard
STAPHYLOCOCCUS AUREUS	ABSENCE				Manufacture's Standard
PSEUDOMONAS AERUGINOSA	ABSENCE				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				

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: 43550 C. H. S. P. CO., LTD. (China) Manufacturer Batch: TRER-20240101 Manufacturer original CoA available under request

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Silvia Sancho-Tello Ripoll
Technical Director.

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