

Tretinoin

CODE ARTICLE: 98122	BATCH: 0131691	Active pharmaceutical ingredient
TEST DATE: 04/10/2024	TEST: QC-00268655	
EXPIRY DATE: 25/03/2027	FABRICATION DATE: 26/03/2024	MR: 300,42
CAS: [302-79-4]	FORMULA: C20H28O2	
SYNONYMS / BOTANICAL NAME: Tretinoína; Ácido trans-retinoico; Tretinoíno; Vitamina A ácida		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS	-		Crystal powder	PH.EUR.*
COLOUR	PASS	-		Yellow or slightly orange	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	PASS	-		Slightly soluble in ethanol (96 per cent)	PH.EUR.*
SOLUBLE	PASS	-		Moderately soluble in methylene chloride	PH.EUR.*
INSOLUBLE	PASS	-		Practically insoluble in water	PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	PASS				PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	<1,0	%		<=1,0	PH.EUR.*
UNSPECIFIED IMPURITIES	<0,2	%		<=0,2	PH.EUR.*
ISOTRETINOIN	N.D.	%		<=0,5	PH.EUR.*
LOSS ON DRYING	0,03	%		<=0,5	PH.EUR.*
SULPHATED ASHES	0,04	%		<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,5	%	98,0	102,0	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
ETHYL ACETATE	674	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	PASS				
Elemental Impurities ICHQ3D	PASS				

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-20240303 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



Tretinoin

CODE ARTICLE: 98122	BATCH: 0131691	Active pharmaceutical ingredient
TEST DATE: 04/10/2024	TEST: QC-00268655	
EXPIRY DATE: 25/03/2027	FABRICATION DATE: 26/03/2024	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
------	---------	-------	-----	-----	--------



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.

Manufacturer: 43550 C. H. S. P. CO., LTD. (China) Manufacturer Batch: TRER-20240303 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

