

CERTIFICATE OF ANALYSIS

Product Name:	TRETINOIN ✓	Mfg. Date:	Jul.14 th ,2018
Batch No.:	TRER-20180702 ✓	Re-test Date:	Jul.13 th ,2021
Quantity:	37.13kg	Report Date:	Jul.24 th ,2018
Analysis Reference:	EP9.0 incl. In-house specifications		

Item		Specification	Result
Appearance		Yellow or light-orange, crystalline powder	Yellow crystalline powder
Identification		IR: Comparing with the spectrum obtained with Tretinoin CRS	Conform
Melting point		182.0°C ± 2.0°C	183.0°C
Loss on drying		≤ 0.5%	0.03%
Sulfated ash		≤ 0.1%	0.04%
Heavy metals		≤ 20ppm	< 20ppm
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤ 0.5%	Undetected
	Unspecified impurities	≤ 0.2%	Undetected
	Single unknown impurity	≤ 0.10%	< 0.05%
	Total impurities	≤ 1.0%	< 0.05%
Residual solvents	Acetaldehyde	≤ 15ppm	< 15ppm
	Ethyl acetate	≤ 5000ppm	421ppm
Microbiological limit tests	TAMC	≤ 100CFU/g	< 20 CFU/g
	TYMC	≤ 100CFU/g	< 20 CFU/g
	Staphylococcus aureus and P. aeruginosa	Absent	Absent
Assay		98.0% ~ 102.0% (dried substance)	100.1%

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ACIDO RETINOICO GRANUL

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Fecha Entrada: 29-08-2018

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Conclusion: Conform to EP9.0 incl. In-house specifications.

QC by: 朱真
2018.01.24

QC director by: R. J. [Signature]
2018-07-24

QA by: 2010725

Approved by: 21/03/22
2018.07.28