



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

METAPHARMACEUTICAL

Product Name: TRETINOIN

N DE LOTE:

0310525

Batch No.: TRER-20250104

Mfg. Date: Jan.12th.2025

Quantity: 45.12kg

Retest Date: Jan.11th.2028

Test No.: P250023

Report Date: Jan.23rd.2025

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21/05/2025

Analysis Reference: EP11.0 incld. 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	183.5°C
Loss on drying		≤0.5%	0.05%
Sulfated ash		≤0.1%	0.05%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Impurity G <0.05%
	Total impurities	≤1.0%	0.08%
Residual solvents	Ethyl acetate	≤5000ppm	813ppm
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)	100.2%
Conclusion: Conform to EP11.0 incld. In-house specifications			

QC by: *谢玲*
2025.01.23

QC director by: *张希光*
2025.01.23

QA by: *张御贤*
2025.02.06

Approved by: *席奎*
2025.02.07

Manufacturing site: Chongqing Huapont Shengchem Pharm. Co., Ltd.

Address of Manufacturing site: No.666 Rongjun Road, Nanjin Avenue, Hechuan District, Chongqing, China (401520)

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