



CHONGQING HUAPONT PHARM. CO., LTD.

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28/03/2024

CERTIFICATE OF ANALYSIS METAPHARMACEUTICAL

N DE LOTE:

0400324

Product Name: TRETINOIN

Batch No.: TRER-20240101

Mfg. Date: Jan.20th.2024

Quantity: 40.32kg

Retest Date: Jan.19th.2027

Test No.: P240045

Report Date: Jan.31st.2024

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	183.0°C
Loss on drying		≤0.5%	0.09%
Sulfated ash		≤0.1%	0.02%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Impurity G 0.06%
	Total impurities	≤1.0%	0.09%
Residual solvents	Ethyl acetate	≤5000ppm	611ppm
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)	100.3%
Conclusion: Conform to EP11.0 incld. In-house specifications			

QC by: Wang J.
2024.01.31

QC director by: Wang J.
2024.01.31

QA by: Wang J.
2024.02.01

Approved by: Wang J.
2024.02.01

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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