



METAPHARMACEUTICAL

CHONGQING HUAPONT PHARM. CO., LTD.

N DE LOTE:

0291024

31/10/2024

Tel: 86-23-67886928, 86-23-42724382 Fax: 86-23-67886927 Email: api@huapont.cn Website: www.huapont.cn

CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN

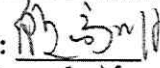
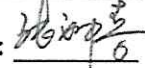
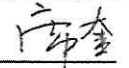
Batch No.: TRER-20240303 Mfg. Date: Mar.26th.2024

Quantity: 43.32kg Retest Date: Mar.25th.2027

Test No.: P240153 Report Date: Apr.10th.2024

Analysis Reference: EP11.0 incld. In-house specifications

Item		Specification	Result
Appearance		Yellow or light-orange, crystalline powder	Light-orange crystalline powder
Identification		IR: Comparing with the spectrum obtained with Tretinoin CRS	Conform
Melting point		182.0°C±2.0°C	182.5°C
Loss on drying		≤0.5%	0.02%
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%	0.09%
Residual solvents	Ethyl acetate	≤5000ppm	674ppm
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)	99.6%
Conclusion: Conform to EP11.0 incld. In-house specifications			

QC by: 
2024.04.10QC director by: 
2024.04.10QA by: 
2024.04.11Approved by: 
2024.04.11

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

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

COA Ver. No. RQA-S-TRER002-2(12)