



CHONGQING HUAPONT PHARM. CO., LTD.

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

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21/09/2022

CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN
 Batch No.: TRER-20220203 Mfg. Date: Feb.20th.2022
 Quantity: 46.42kg Retest Date: Feb.19th.2025
 Test No.: P22093 Report Date: Feb.28th.2022
 Analysis Reference: EP10.0 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	182.5°C
Loss on drying		≤0.5%	0.08%
Sulfated ash		≤0.1%	0.02%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Impurity D <0.05%
	Total impurities	≤1.0%	0.11%
Residual solvents	Ethyl acetate	≤5000ppm	492ppm
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%
Conclusion: Conform to EP10.0 incld. In-house specifications.			

QC by: *[Signature]*
2022.02.28

QC director by: *[Signature]*
2022.02.28

QA by: *[Signature]*
2022.03.09

Approved by: *[Signature]*
2022.03.17

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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