



CHONGQING HUAPONT PHARM. CO., LTD.

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



F&A PHARMA

F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D - 46286 Dorsten • Germany
Phone: +49 (0) 2369-9261947 • Fax: +49 (0) 2369-9261950

CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN
Batch No.: TRER-20201102 Mfg. Date: Nov.08th.2020
Quantity: 45.36kg Retest Date: Nov.07th.2023
Test No.: TRER201102 Report Date: Nov.17th.2020
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	183.5°C
Loss on drying		≤ 0.5%	0.02%
Sulfated ash		≤ 0.1%	0.01%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤ 0.5%	Undetected
	Unspecified impurities	≤ 0.2%	Undetected
	Total impurities	≤ 1.0%	< 0.05%
Residual solvents	Ethyl acetate	≤ 5000ppm	311ppm
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)	100.4%
Conclusion: Conform to EP10.0 incld. In-house specifications.			

QC by: 杨
2020.11.17

QC director by: 何
2020.11.17

QA by: 李
2020.11.19

Approved by: 刘
2020.11.24

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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