

23/12/2021.



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN

Batch No.: TRER-20210803 Mfg. Date: Jul.31st.2021

Quantity: 45.70kg Retest Date: Jul.30th.2024

Test No.: TRER210703 Report Date: Nov.10th.2021

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	182.0°C
Loss on drying	≤0.5%	0.04%
Sulfated ash	≤0.1%	0.04%
Related substances (Reporting threshold 0.05%)	Isotretinoin ≤ 0.5%	Undetected
	Unspecified impurities ≤ 0.2%	Undetected
	Total impurities ≤ 1.0%	0.12%
Residual solvents	Ethyl acetate ≤ 5000ppm	402ppm
	Acetaldehyde ≤ 15ppm	< 15ppm
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)	100.0%
Conclusion: Conform to EP10.0 incld. In-house specifications.		

QC by: 2021.11.10 QC director by: 2021.11.10 QA by: 2021.11.10 Approved by: 2021.11.10

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

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