

METAPHARMACEUTICAL

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18/03/2022



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN
Batch No.: TRER-20210805 Mfg. Date: Aug.02nd.2021
Quantity: 45.80kg Retest Date: Aug.01st.2024
Test No.: TRER210802 Report Date: Feb.10th.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%	0.05%
Sulfated ash	≤0.1%	0.05%
Related substances (Reporting threshold 0.05%)	Isotretinoin ≤0.5%	Undetected
	Unspecified impurities ≤0.2%	Undetected
	Total impurities ≤1.0%	0.11%
Residual solvents	Ethyl acetate ≤5000ppm	449ppm
	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)	99.9%
Conclusion: Conform to EP10.0 incld. In-house specifications.		

QC by: [Signature]
2022.02.10

QC director by: [Signature]
2022.02.10

QA by: [Signature]
2022.02.11

Approved by: [Signature]
2022.02.11

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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