



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN Mfg. Date: Nov.13th.2018
Batch No.: TRER-20181101 Retest Date: Nov.12th.2021
Quantity: 36.81kg Report Date: Nov.23rd.2018
Analysis Reference: EP9.0 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%	0.03%
Sulfated ash		≤0.1%	0.03%
Heavy metals		≤20ppm	<20ppm
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Impurity G <0.05%
	Single unknown impurity	≤0.10%	<0.05%
	Total impurities	≤1.0%	0.07%
Residual solvents	Acetaldehyde	≤15ppm	<15ppm
	Ethyl acetate	≤5000ppm	481ppm
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 EP9.0 incld. In-house specifications.			

QC by: 朱英
2018.11.23

QC director by: 王成明
2018.11.23

QA by: 李波波
2018.11.24

Approved by: 王成明
2018.11.24

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

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