



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN Mfg. Date: Nov.08th.2019
 Batch No.: TRER-20191102 Retest Date: Nov.07th.2022
 Quantity: 35.73kg Report Date: Jan.13th.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	183.0°C
Loss on drying		≤0.5%	0.05%
Sulfated ash		≤0.1%	0.04%
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	710ppm
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: 8/kk QC director by: 12/30/13 QA by: (signature) Approved by: 21/13/2
 2020.01.13 2020.01.13 2020.01.13 2020.01.13

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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