



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN Mfg. Date: Feb.22nd.2019
Batch No.: TRER-20190202 Retest Date: Feb.21st.2022
Quantity: 38.43kg Report Date: Mar.06th.2019
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	183.0°C
Loss on drying		≤ 0.5%	0.04%
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%	0.10%
Residual solvents	Acetaldehyde	≤ 15ppm	< 15ppm
	Ethyl acetate	≤ 5000ppm	569ppm
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)	100.2%
Conclusion: Conform to EP9.0 incld. In-house specifications.			

QC by: 2019.03.06 QC director by: 2019.03.07 QA by: 2019.03.12 Approved by: 2019.03.13

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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