



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN Mfg. Date: Sep.26th.2017
Batch No.: TRER-20170902 Retest Date: Sep.25th.2020
Quantity: 38.35kg Report Date: Oct.11th.2017
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%	0.06%
Residual solvents	Acetaldehyde	≤15ppm	<15ppm
	Ethyl acetate	≤5000ppm	588ppm
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 EP9.0 incld. In-house specifications.

QC by: 张
2017.10.11

QC director by: 张
2017.10.11

QA by: 王
2017.10.11

Approved by: 李
2017.10.11



Fecha Entrada: 12-12-2017
94349
Kg
ACIDO RETINOICO GRANUL



Lot: 0072434