



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN ✓ Mfg. Date: Dec.09th.2016
Batch No.: TRER-20161203 ✓ Retest Date: Dec.08th.2019 ✓
Quantity: 9.23kg Report Date: Jan.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	183.0°C
Loss on drying		≤0.5%	0.06%
Sulfated ash		≤0.1%	0.02%
Heavy metals		≤20ppm	<20ppm
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Undetected
	Single unknown impurity	≤0.10%	<0.05%
	Total impurities	≤1.0%	<0.05%
Residual solvents	Acetaldehyde	≤15ppm	<15ppm
	Ethyl acetate	≤5000ppm	648ppm
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: 朱英
2017.01.11

QC director by: 何志明
2017.01.11

QA by: 李波
2017.01.12

Approved by: 刘晓红
2017.01.12

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

Address of Manufacturing site: No.666 Rongjun Road, Nanjin Avenue, Hechuan District, Chongqing, China (401520)

COA Ver. No. RQA-S-TRER002-2(06)

ACIDO RETINOICO GRANUL
Kg
94349
02-03-2017
8 432780 943499
Lote: 0065223
QC-00182412

2017-01-11
300.42
C20H28O2