



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: 李英
2017.10.11

QC director by: 张小明
2017.10.11

QA by: 王小红
2017.10.11

Approved by: 李小明
2017.10.11

Fecha Entrada: 03-04-2018
94349

Kg
ACIDO RETINOICO GRANUL



Lote: 0075304

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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