CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name:	TRETINOIN	Mfg. Date:	Jul.14th.2018
Batch No.:	TRER-20180702	Retest Date:	Jul.13th.2021
Quantity:	37.13kg	Report Date:	Jul.24th.2018
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℃±2.0℃	183.0℃
Loss on drying		≤0.5%	0.03%
Sulfated ash		≤0.1%	0.04%
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	421ppm
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)	100.1%

Conclusion: Conform to EP9.0 incld. In-house specifications.

Kg
ACIDO RETINOICO GRANEL
Fecha Entrada: 29-08-2018
94349
Lote: 00786661
QC-00199942

QC by: 2018.07.24 QC director by: 2018.07.24 QA by: 2018.07.25 Approved by: 2018.07.25