



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN
Batch No.: TRER-20151004
Quantity: 10.55kg
Analysis Reference: EP8.0 incld. In-house specifications

Mfg. Date: Oct.12th.2015
Retest Date: Oct.11th.2018
Report Date: May.19th.2016

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%	0.02%
Sulfated ash		≤ 0.1%	0.01%
Heavy metals		≤ 20ppm	< 20ppm
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤ 0.5%	Undetected
	Unspecified impurities	≤ 0.2%	Impurity D < 0.05%
	Single unknown impurity	≤ 0.10%	< 0.05%
	Total impurities	≤ 1.0%	0.07%
Residual solvents	Acetaldehyde	≤ 15ppm	< 15ppm
	Ethyl acetate	≤ 5000ppm	960ppm
Microbiological limit tests	TAMC	≤ 100CFU/g	< 10 CFU/g
	TYMC	≤ 100CFU/g	< 10 CFU/g
	Staphylococcus aureus and P. aeruginosa	Absent	Absent
Assay		98.0% ~ 102.0% (dried substance)	100.1%
Conclusion: Conform to EP8.0 incld. In-house specifications.			

ATENCIÓN: Este producto es un medicamento. No debe ser utilizado sin la supervisión de un profesional de la salud. Lea atentamente el prospecto que acompaña al producto.

ACIDO RETINOICO GRANULADO

17-06-2016 84349

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Lote: 0058379

QC by: [Signature] QC director by: [Signature] QA by: [Signature] Approved by: [Signature]
2016.05.19 2016.05.19 2016.05.19 2016.05.19