CHONGQING HUAPONT PHARM. CO., LTD.

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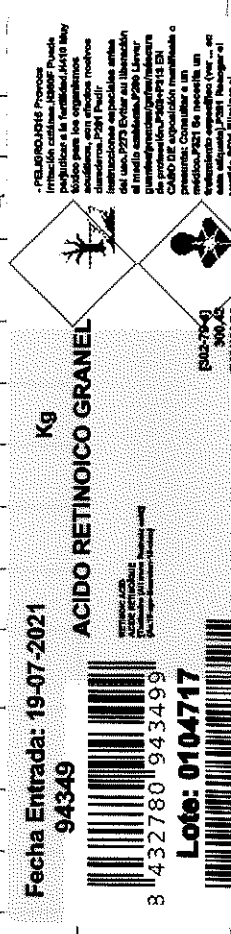
CERTIFICATE OF ANALYSIS

Product Name:	TRETINOIN		
Batch No.:	TRER-20201104	Mfg. Date:	Nov.10th.2020
Quantity:	45.48kg	Retest Date:	Nov.09th.2023
Test No.:	TRER201104	Report Date:	Nov.24th.2020
Analysis Reference:	EP10.0 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%	0.02%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤0.5%	Undetected
	Unspecified impurities	≤0.2%	Undetected
	Total impurities	≤1.0%	<0.05%
Residual solvents	Ethyl acetate	≤5000ppm	300ppm
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)	100.3%

Conclusion: Conform to EP10.0 incld. In-house specifications.



QC by: 2020.11.24 QC director by: 2020-11-24 QA by: 2020.11.26 Approved by: 2020.11.28