CHONGQING HUAPONT PHARM. CO., LTD.
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CERTIFICATE OF ANALYSIS

Product Name: TRETINOIN

Batch No.: TRER-20200401 Mfg. Date: Apr.16th.2020

Quantity: 36.29kg Retest Date: Apr.15th.2023

Test No.: TRER200401 Report Date: Apr.28th.2020

Analysis Reference: USP42 incld. In-house specifications

Item		Specification	Result
Appearance		Yellow or light-orange, crystalline powder	Yellow crystalline powder
Identification		IR: Identical versus reference spectrum	Conform
		UV: Absorptivity at 352nm do not differ by more than 3.0%	Conform
Loss on drying		≤0.5%	0.04%
Residue on ignition		≤0.1%	0.02%
Heavy metals		≤0.002%	<0.002%
Related substances (Reporting threshold 0.05%)	Isotretinoin	≤5.0%	Undetected
	Impurity G	≤0.2%	Undetected
	Single unknown impurity	≤0.10%	<0.05%
	Total impurities (Except Isotretinoin)	≤0.5%	0.07%
Residual solvents	Acetaldehyde	≤15ppm	<15ppm
	Ethyl acetate	≤5000ppm	635ppm
Microbiological limit tests	TAMC	≤100CFU/g	<20 CFU/g
	TYMC	≤100CFU/g	<20 CFU/g
	Staphylococcus aureus and P. aeruginosa	Absent	Absent
Assay		97.0%~103.0% (dried substance)	99.8%
Conclusion: Conform to USP42 incld. In-house specifications.			

※ All other solvents as discussed in USP<467>/ICH guidelines are not used at any time during the production process except for those already listed in the COA and those having been proved to be removed consistently by the validated process procedure.

QC by: 2020.04.28 QC director by: 2020.04.28 QA by: 2020.04.29 Approved by: 2020.04.30

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