



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: ISOTRETINOIN

Batch No.: IST-20250104 Mfg. Date: Jan.01st.2025

Quantity: 53.56kg Retest Date: Dec.31st.2027

Test No.: P250001 Report Date: Jan.22nd.2025

Analysis Reference: Ph. Eur. 11.0 incld. In-house specifications

Signature

23/03/2025

Item		Specification	Result
Appearance		Yellow or light orange, crystalline powder	Light orange, crystalline powder
Identification		Examined by infrared absorption spectrophotometry comparing with the spectrum obtained with Isotretinoin CRS	Conform
Loss on drying		≤0.5%	0.07%
Sulfated ash		≤0.1%	0.02%
Related substances (Reporting threshold 0.05%)	Tretinoin (A)	≤0.2%	0.07%
	Unspecified Impurities	≤0.10%	RRT≈0.46 0.05%
	Total impurities	≤0.5%	0.13%
Residual solvents*	Hexane	≤50ppm	<0.2ppm (LOD)
	Acetonitrile	≤410ppm	<4.5ppm (LOD)
	Methanol	≤2000ppm	560ppm
	Ethyl acetate	≤2000ppm	<3.0ppm (LOD)
Microbiological limit tests	TAMC	≤1000CFU/g	<20 CFU/g
	TYMC	≤100CFU/g	<20 CFU/g
	Escherichia coli	Absent	Absent
Assay		98.0%~102.0% (dried substance)	100.2%
Conclusion: Conform to Ph. Eur. 11.0 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: *Signature*QC director by: *Signature*QA by: *Signature*Approved by: *Signature*

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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