



CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: ISOTRETINOIN
 Batch No.: IST-20130303
 Quantity: 51.66kg
 Analysis Reference: Ph. Eur. 7.0, Incd, In-house specifications

Mfg. Date: Mar. 20th, 2013
 Retest Date: Mar. 19th, 2015
 Report Date: Mar. 28th, 2013

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
Related substances (Reporting threshold 0.05%)	Tretinoin (A)	≤0.5%	0.16%
	13-cis-4-oxoretinoic acid (H)	≤0.3%	<0.05%
	13-cis-4-hydroxyretinoic acid (I)	≤0.3%	Undetected
	Unspecified impurities	≤0.2%	Impurity G Undetected
	Single unknown impurity	≤0.10%	≤0.05%
	Total impurities	Before the principal peak ≤0.7% After the principal peak ≤1.0%	0.05% 0.16%
Heavy metals		≤20ppm	≤20ppm
Loss on drying		≤0.5%	0.02%
Sulfated ash		≤0.1%	0.01%
Residual solvents*	Acetonitrile	≤110ppm	≤17.85ppm (LOD)
	Methanol	≤2000ppm	800ppm
	Ethyl acetate	≤2000ppm	≤12.00ppm (LOD)
	Hexane	≤50ppm	≤0.90ppm (LOD)
Assay		98.0%-102.0% (dried substance)	99.8%
Conclusion: Conform to Ph. Eur. 7.0, Incd, In-house specifications.			

All other solvents as discussed in USP <167>/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]
 2013.03.28 2013.03.28 2013.03.28 2013.03.28

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

Address of Manufacturing site: No. 666 Rongshu Road, Nanjin Avenue, Hechuan District, Chongqing, China (401520)

COA Ver. No.: RQA-S-IST003-1(03)