CHONGQING HUAPONT PHARM. CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name:	ISOTRETINOIN	Mfg. Date:	Mar.20th.2018
Batch No.:	IST-20180306	Retest Date:	Mar.19th.2020
Quantity:	51.26kg	Report Date:	Mar.29th.2018
Analysis Reference:	Ph. Eur.9.5. incld. In-house specifications		

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%	0.04%
Sulfated ash		≤0.1%	0.01%
Related substances (Reporting threshold 0.05%)	Tretinoin (A)	≤0.2%	<0.05%
	Unspecified impurities	≤0.10%	RRT≈0.47 0.05%
	Total impurities	≤0.5%	0.11%
Residual solvents*	Hexane	≤50ppm	<0.2ppm（LOD）
	Acetonitrile	≤410ppm	<4.5ppm（LOD）
	Methanol	≤2000ppm	561ppm
	Ethyl acetate	≤2000ppm	<3.0ppm（LOD）
Assay		98.0%~102.0% (dried substance)	99.8%
Conclusion: Conform to Ph. Eur.9.5. 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: 2018.03.29 QC director by: 2018.03.29 QA by: 2018.03.30 Approved by: 2018.03.30

Manufacturing site: Chongqing Huapont Shengchem Pharm. Co., Ltd.
Address of Manufacturing site: No.666 Rongjun Road, Nanjin Avenue,Hechuan District, Chongqing, China (401520)
COA Ver. No.: RQA-S-IST003-1(20180321)