台州天禄生物医药有限公司 Taizhou Tyloo Biopharm Co.,Ltd

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CERTIFICATE OF ANALYSIS

Name of product	Isotretinoin	MFG. Date	July.10,2017
Batch No.	TYL20170710	EXP. Date	July.09,2019
QTY.	97kg	Test Standard	EP8
Test Items	Specifications		Result
Appearance	yellow or light orange crystalline powder		Conforms
Identification	IR,UV		Conforms
Loss on drying	≤0.5%		0.01%
Sulphated ash	≤0.1%		0.03%
Heavy metals	≤20ppm		Conforms
Related substances:			
Tretinoin	≤2.0%		0.1%
Total of other	≤0.5%		0.3%
impurities			
Assay	98.09	%-102.0%	99.9%
Storage	Preserve in tight co	ontainers, preferably under	an atmosphere of
	nitrogen, protected from light, stored at 25° C±2°C.		
Conclusion	It complies with all requirements of USP36 standard		

QC.Manager:叶晓培

Checked by:刘长明

Analysed by:于明明

