



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
<i>Test Items</i>	<i>Specifications</i>		<i>Result</i>
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 impurities	≤0.5%		0.3%
Assay	98.0%-102.0%		99.9%
Storage	Preserve in tight containers,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

