



Jinan Hongfangde Pharmatech Co., Ltd.  
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## 质检单

### CERTIFICATE OF ANALYSIS

Product Name	Raloxifene HCL CAS:82640-04-8		
Manufacture Date	2019-06-07	Batch No.	20190607
Report Date	2019-06-18	Quantity	16.6kg

Items	Standard		Results
Appearance	Yellowish powder		Comply
Identification	IR		Comply
	It meets the requirements of the test for Chloride		Comply
Solubility	Soluble in 10% sodium hydroxide solution, slightly soluble in methanol, insoluble in water		Comply
Assay	98.5%~101.5%		99.50%
Impurities	Raloxifene 3,7-Diketone at RRT=0.74 impurity	≤0.2%	Comply
	Other single impurity	≤0.1%	0.06%
	Total impurities	≤0.5%	0.21%
Residual solvents	Methanol	≤3000ppm	878ppm
	Acetone	≤5000ppm	Not detected
	Methylene Chloride	≤600ppm	Not detected
	n-Hexane	≤290ppm	Not detected
	Benzene	≤2ppm	Not detected
	Dimethyl Formamide	≤880ppm	Not detected
Loss on drying	≤0.5%		0.20%
Residue on ignition	≤0.1%		Comply
Heavy metals	≤10ppm		Comply
Storage	Preserve in well-closed containers and Protected from light. Store at room temperature		
Determination	Complies with USP40 standard		

Analyst :yalan

Checker:wuhao

Supervisor :wanghongfu



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