



浩信药业
HAOSUN PHARMA

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CERTIFICATE OF ANALYSIS

Check No.: FP-12-1203001

Product Name:	Cimetidine	Batch No.:	HS1220120301
Quantity:	235.2kg	Manufacturing Date:	2012-3-19
Packing:	25kg/drum	Retest Date:	2015-3-18
Test Standard:	USP32	Report Date:	2012-3-20

Items	Specifications	Results
Characters		
Appearance	White or off-white crystalline powder, odorless, bitter taste	White crystalline powder
Solubility	Freely soluble in methanol and dilute hydrochloric acid, soluble in ethanol, sparingly soluble in isopropanol, slightly soluble in water	Conform
Identification		
IR	The sample's IR spectrum is in accordance with that of cimetidine R.S.	Conform
UV	The UV absorption spectrum of sample exhibits max and min at the same wavelengths as that of Cimetidine R.S.	Conform
Melting range	139°C to 144°C	141.0°C to 142.0°C
Loss on drying	Not more than 1.0%	0.08%
Residue on ignition	Not more than 0.2%	0.10%
Heavy metals	Not more than 0.002%	<0.002%
Related substances		
Individual impurity	Not more than 0.2%	0.14%
Total impurities	Not more than 1.0%	0.53%
Residue solvents		
Ethanol	Not more than 5000ppm	<5000ppm
Assay (On the dried basis)	98.0%~102.0%	99.91%

Conclusion: Conform to USP32

QC Manager: 郭香玲
2012年03月20日

Rechecker: 李亚琪
2012年03月20日

Checker: 纪政
2012年03月20日

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