

WUJI KAILI PHARMACEUTICAL CO., LTD.
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CERTIFICATE OF ANALYSIS

PRODUCT: CIMETIDINE		
LOT NO: 20111237	QUANTITY: 5G	PACKAGING: PLASTIC BAG
MANUFACTURE DATE: DEC. 24, 2011		RETEST DATE: DEC. 24, 2014

Specification		Standard	Test Results
Characters		A white or almost white crystalline powder shows polymorphism	Conforms
Identification	Melting Point	Should between 139°C and 144°C	140.0~141.3°C
	Infrared Absorption	Should conform	Conforms
	Examined by TLC	Should conform	Conforms
Appearance of solution		Should conform	Conforms
Related Substances (by HPLC)		Cimetidine carboxamide: NMT 0.2%	<0.05%
		Any other detectable impurity: NMT 0.10%	0.05%
		Total impurities: NMT 0.5%	0.12%
Heavy Metals		Not more than 20ppm	< 20ppm
Loss on Drying		Not more than 0.5%	0.11%
Sulphated Ash		Not more than 0.2%	0.049%
Residual Solvents	Ethanol	Not more than 5000ppm	Conforms
Assay (C ₁₀ H ₁₆ N ₂ S)		98.5% ~ 101.5%	99.80%
Conclusion		Complies with COS quality and current in-house specs.	

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QC REVIEW:

QA APPROVAL:

