

F00258

CL 2009 - Dopl. 2010

2009-TS1
283511Certif. n. 04040512/535
Plaintiff do: 24.12.2014

handed over by:

VIVATIS PHARMA
Mühlendamm 66 a - D-22087 Hamburg
Tel. +49(0)40 - 236 90 90 Fax +49(0)40 - 236 90 936

WUKI KAILI PHARMACEUTICAL CO., LTD.
ZHOUTIE TOWN, YIXING CITY, JIANGSU PROVINCE, P.R. CHINA 214261

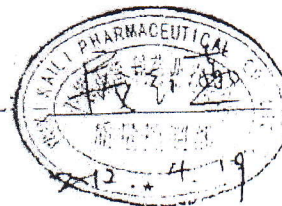
CERTIFICATE OF ANALYSIS

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 ₁₃ H ₁₆ N ₆ S)		98.5% ~ 101.5%	99.80%
Conclusion		Complies with COS quality and current in-house specs.	

Tel.: +86-510-87501816, 87506633

Fax.: +86-510-87501816, 87501812

QC REVIEW: QA APPROVAL: 

CORRESPONDAL LOT. 1207-

2014/13