

F00258

CL 2009 - Dopl. 2010

2009-TS1
283511Certif. n. 04040512538
Plaintiff do: 24.12.2014

handed over by:

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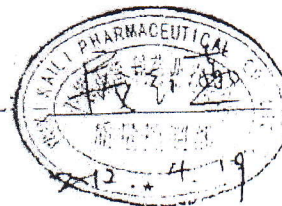
CERTIFICATE OF ANALYSIS

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 ($C_{13}H_{16}N_6S$)		98.5% ~ 101.5%	99.80%
Conclusion		Complies with COS quality and current in-house specs.	

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QC REVIEW: QA APPROVAL: 

CORRESPONDAL LOT. 1207-

2014-13