

WUXI KAILI PHARMACEUTICAL CO., LTD
ZHOUTIE TOWN, YINING CITY, JIANGSU PROVINCE, P.R. CHINA 214261

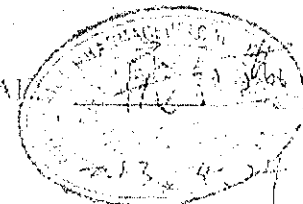
CERTIFICATE OF ANALYSIS

PRODUCT: CIMETIDINE			
LOT NO: 20130314		QUANTITY: 100KG	PACKAGING: 25KG/DRUM
MANUFACTURE DATE: MAR. 17, 2013		RETEST DATE: MAR. 17, 2016	
Specifications	Standard	Test Results	
Characters	A white or almost white crystalline powder shows polymorphism	Conforms	
Identification	Melting Point	Should between 139°C and 144°C	
	Infrared Absorption	Should conform	
	Examined by TLC	Should conform	
Appearance of solution	Should conform	Conforms	
Related Substances (by HPLC)	Cimetidine carboxamide: NMT 0.2%	0.06%	
	Any other detectable impurity: NMT 0.10%	0.02%	
	Total impurities: NMT 0.5%	0.24%	
Heavy Metals	Not more than 20ppm	< 20ppm	
Loss on Drying	Not more than 0.5%	0.10%	
Sulphated Ash	Not more than 0.2%	0.030%	
Residual Solvents	Ethanol	Not more than 5000ppm	
Assay (C ₁₁ H ₁₃ N ₃ S)	98.5% - 101.5%	99.83%	
Conclusion	Complies with COS quality and current in-house specs		

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QC REVIEW: 

QA APPROVAL: 

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13E13-T11

Director Técnico 