



SHIJIAZHUANG POLEE PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Product name: Cimetidine

Analysis in accordance: USP43

Batch No.: 2106033C03

Quantity: 500kg

Package: 25kg/drum

Date of manufacturing: 2021/06/05

Date of expiry: 2024/06/04

Item	Standard	Result
Appearance	White or almost white Crystalline	
	Powder odourless, bitter taste	Conform
Identification		
A:(IR)	Conform to USP Cimetidine RS	Conform
B:(UV)	Conform to USP Cimetidine RS	Conform
Assay (calculated on the dried basis)		
	98.0-102.0%	99.9%
Impurities		
Residue on ignition	NMT 0.2%	Conform
Organic impurities	Any Individual impurity NMT 0.2%	NMT 0.2%
	Total impurities NMT 1.0%	NMT 1.0%
Melting range or Temperature	139~144°C	141-143°C
Loss on drying	NMT 1.0%	0.17%
Residual solvents (ethanol)	NMT 0.5%	NMT 0.5%



Conclusion: Conforming to the standard of USP43.

Qualified Person:

Checker:

Analyst: