



CHANGZHOU PHARMACEUTICAL FACTORY

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CERTIFICATE OF ANALYSIS

We hereby certify that the following product has been manufactured by our factory and that the relative statements below are true and correct.

Product :CAPTOPRIL

Manufacturing Date :Aug. 26, 2011

Quantity : 326 KG

Expiry Date : Aug. 26, 2014

Batch NO. :CS0903

Lote Ueto COJ1211

Tests	Specifications	Results
Description	White to off – white crystalline powder with a characteristic sulfide – like odor.	Complies
Identification	IR: similar to Reference Standard	Complies
Appearance of solution	Clear and colourless	Complies
Specific Rotation	-127° to -132°	-131°
Loss on Drying	≤0.5%	0.02%
Sulphated ash	≤0.2%	0.1%
Heavy metals	≤0.002%	Complies
pH	2.0 to 2.6	2.1
Impurity F	NMT 0.2%	0.07%
Related Substances	Impurity A: NMT 1.0%	0.23%
	Impurity B: NMT 0.15%	Undetected
	Impurity C: NMT 0.15%	Undetected
	Impurity D: NMT 0.15%	0.07%
	Impurity E: NMT 0.15%	Undetected
	Single largest unidentified impurity: NMT 0.10%	Undetected
	Total impurities: NMT 1.2%	0.23%
Assay(Anhydrous)	98.0% to 101.5%	100.1%

The results above meet all requirements under CAPTOPRIL in EP7.0

Analysis No.110192

Signature:

Date: Sep. 06, 2011

Quality Control Department

