FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
L14 100245
13/1/14
Director Técnico

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 : Jan. 02, 2014

Quantity : 411.7 KG

Retest Date : Jan. 02, 2017

Batch NO. : EC140101

Tests	Specifications	Results
Description	White or almost white crystalline powder.	Complies
Identification	IR: similar to Reference Standard	Complies
*Solubility	Soluble in water, Freely soluble in methylenechloride and methanol	Complies
Appearance of solution	Clear and colourless	Complies
Specific Optical Rotation	-127° to -132° (Dried Substance)	-129°
Loss on Drying	≤0.5%	0.08%
Sulphated ash	≤0.2%	0.03%
Heavy metals	≤0.002%	Complies
pH	2.0 to 2.6	2.2
Impurity F	NMT 0.2%	0.10%
Related Substances	Impurity A: NMT 1.0% Impurity B: NMT 0.15% Impurity C: NMT 0.15% Impurity D: NMT 0.15% Impurity E: NMT 0.15% Impurity J: NMT 0.2% Single largest unidentified impurity: NMT 0.10% Total impurities: NMT 1.2%	0.19% Undetected Undetected Undetected Undetected Undetected 0.05% 0.24%
Assay(Dried Substance)	98.0% to 101.5%	100.1%

Note: * - is according to clients' requirements

The results above meet all requirements under CAPTOPRIL in EP7.4

Analysis No.C-140003

Signature:

Date: Jan. 13, 2014

Quality Control Department