FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
13E15-B40
Director Técnico

CHANGZHOU YABANG PHARMACEUTICAL CO., LTD.

常 州 亚 邦 制 药 有 限 公 司

Add: Liangchang East Road 6# Jintan, Changzhou, Jiangsu, China

CERTIFICATE OF ANALYSIS

Product name: PROPRANOLOL HCL

Batch No.: M130104 Manufacture Date: 14 Jan, 2013

Quantity: 100kg Expiry Date: 13 Jan, 2016

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	A white or almost white powder.	Conform
Solubility	Soluble in water and in ethanol (96 %).	Conform
IDENTIFICATION		
A	Melting point: 163 °C to 166 °C.	163.5~164.5°C
B	Examine by infrared absorption spectrophotometry, comparing with the spectrum obtained with *propranolol hydrochloride CRS*.	Conform
C	Examine by thin-layer chromatography. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Conform
D	It gives reaction (a) of chlorides.	Conform
TESTS		
Appearance of solution	The solution is clear and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour.	Conform
Acidity or alkalinity	Add 0.2 ml of *methyl red solution R* and 0.2 ml of *0.01 M hydrochloric acid*. The solution is red. Add 0.4 ml of *0.01 M sodium hydroxide*. The solution is yellow.	Conform
Related substances	Any Impurity NMT 0.1%.	0.04%
	The sum of all Impurities NMT 0.4%.	0.10%
Heavy metals	NMT 20ppm.	Conform
Loss on drying	NMT 0.5%.	0.21%
Sulphated ash	NMT 0.1%.	0.07%
Residual Solvents	A. Ethanol: NMT 5000ppm.	Conform
	B. Xylene: NMT 2170ppm.	Conform
ASSAY	99.0%~101.0%	99.6%
Conclusion: Conform to EP7.0		

Quality Control Manager: Checker: Yao Jun Analyst: Mei Li