

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

CHENG FONG CHEMICAL CO., LTD.

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New Taipei City 220, Taiwan (R.O.C.)

Factory : No.19, Gong 4th Rd., Dayuan Dist.,
Taoyuan City 337, Taiwan (R.O.C.)

CERTIFICATE OF ANALYSIS

Director Técnico

Product : Phenylephrine Hydrochloride EP 8		
Lot No : 51001	Quantity : 25 kg x 2	
Manu. Date : Oct. 02, 2015	Retest Date : Oct. 02, 2020	Released Date : Jan. 11, 2016

ITEMS	SPECIFICATION	RESULTS
Characters	A white or almost white, crystalline powder, freely soluble in water and in alcohol. It melts at about 143 °C	White crystalline powder
Identification		
A. Specific optical rotation	It complies with the test for specific optical rotation.	Conforms
B. IR	Accord with the standard spectrum.	Accord
C. Tests of Chloride	Meets the requirements	Conforms
Appearance of solution	Solution S is clear and colourless.	Clear, Colourless
Acidity and alkalinity	To 10 ml of solution S add 0.1 ml of methyl red solution R and 0.2 ml of 0.01 M sodium hydroxide. The solution is yellow. Not more than 0.4 ml of 0.01 M HCl is required to change the colour of the indicator to red.	0.25 ml
Specific optical rotation	- 43 ° ~ - 47 °	- 46.245°
Related substances	Impurity C: NMT 0.1 % Impurity E: NMT 0.1 % Each unknown impurity: NMT 0.10 % Total impurity: NMT 0.2 %	Undetected Undetected Undetected Undetected
Sulphates	NMT 500 ppm	< 500 ppm
Loss on drying	NMT 1.0 %	0.02 %
Sulphated ash	NMT 0.1%	0.05 %
Assay	98.5 ~ 101.0 %	100.45 %
Residual solvents (1) Methanol (2) Ethanol (3) Acetone (4) Isopropanol (5) Methyl isobutylketone (6) Toluene	NMT 3000 ppm NMT 5000 ppm NMT 5000 ppm NMT 5000 ppm NMT 5000 ppm NMT 890 ppm	Undetected Undetected Undetected 288.4 ppm Undetected Undetected
Particle size distribution Retained on ASTM 140 # / 106 µm Retained on ASTM 230 # / 63 µm Retained on ASTM 325 # / 45 µm Tapped density	Code : 051 Informative Informative Informative 0.6~0.9 g/ml	1.2 % 69.7 % 27.7 % 0.76 g/ml
Residual palladium	NMT 10 ppm	Undetected
Plant Manager	Director Q. C.	Analyst
<i>Arthur Chen</i>	<i>Simon Wong</i>	<i>Lin Fang Yu</i>

Q.A. Approval : *Simon Wong*

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