

SHENZHEN ORIENTAL PHARMACEUTICAL CO.,LTD.

No. 43, Dakeng Road, Tongle Village, Longgang District, Shenzhen, China zip:518116
Tel:86-755-84891609 Fax:86-755-84873052 Email:Sales@szoriental.com Web:www.szoriental.com

CERTIFICATE OF ANALYSIS

检验专用章

Product Name: Phenylephrine Hydrochloride	Batch/Lot No: PEH-170717
Manufacturing date: Jul. 21, 2017	Batch Size: 721.1kg

Test	Specification	Result
Characters	White or off-white crystalline powder; Freely soluble in water and in alcohol	Complies
Melting point	About 143°C	142.3~143.4°C
Identification		
A	Corresponding with specific optical rotation	Complies
C(IR)	Corresponding to reference spectrum	Complies
E(Chloride)	Give reaction of chlorides	Complies
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	Comply with the test of acidity and alkalinity	Complies
Specific optical rotation	-43° ~ -47°	-45.2°
Sulfates	≤0.05%	<0.05%
Loss on drying	≤1.0%	0.03%
Sulfated ash	≤0.1%	0.02%
Related substances	Impurities C: ≤0.1%	Not detected
(HPLC)	Impurities E: ≤0.1%	Not detected
	Unspecified impurity: ≤0.10%	0.02%

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Product Name: Phenylephrine Hydrochloride ... Batch/Lot No.: PEH-170717

Test	Specification	Result
	Total impurities: $\leq 0.2\%$	0.06%
Assay	98.5%~101.0% (calculated on the dried basis)	100.1%
Residual solvents	$\leq 0.5\%$ (Isopropanol)	0.003%
	$\leq 0.3\%$ (Methanol)	0.005%
	$\leq 0.5\%$ (Ethanol)	Not detected
Evaluation: Product corresponds with the requirement of EP9.0.		
Remarks: The expiry date is Jul. 20, 2020 (to be understood as recommended date of retesting).		

Director: 刘明全
(signature/date) 2017.08.03

Reviser: 李红
(signature/date) 2017.08.03

Reporter: 黄曼
(signature/date) 2017.08.03