

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

Product Name: Phenylephrine Hydrochloride	Batch/Lot No.: PEH-211229
Manufacturing date: Dec. 25, 2021	Batch Size: 443.5kg

Test	Specification	Result
Appearance	White or almost white crystalline powder	Complies
Solubility	Freely soluble in water and in ethanol (96 percent)	Complies
Melting point	About 143°C	141.8~142.8°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°	-46.1°
Sulfates	≤0.05%	<0.05%
Loss on drying	≤1.0%	0.03%
Sulfated ash	≤0.1%	0.04%
Related substances	Impurities C: ≤0.1%	Not detected
(HPLC)	Impurities E: ≤0.1%	Not detected

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Product Name: Phenylephrine Hydrochloride

Batch/Lot No.: PEH-211229

Test	Specification	Result
	Unspecified impurity : $\leq 0.10\%$	0.04%
	Total impurities : $\leq 0.2\%$	0.16%
Assay	98.5%~101.0% (calculated on the dried basis)	100.2%
Residual solvents	$\leq 0.5\%$ (Isopropanol)	0.014%
	$\leq 0.3\%$ (Methanol)	0.066%
	$\leq 0.5\%$ (Ethanol)	Not detected

Evaluation: Product corresponds with the requirement of EP10.

Remarks: The expiry date is Dec. 24, 2024(to be understood as recommended date of retesting).

Director: 刘巧玲
(signature/date) 2022.03.01

Reviser: 刘巧玲
(signature/date) 2022.03.01

Reporter: 张俊明
(signature/date) 2022-03-01

