



F. & A. PHARMA-Handels-GmbH

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正峰化學製藥股份有限公司

CHENG FONG CHEMICAL CO., LTD.

Office: 8F., No. 2-2, Sec. 2, Nanya W. Rd., Banciao Dist., New Taipei City 220, Taiwan (R.O.C.)

Tel: 886-2-29667811 ~3 Fax: 886-2-29669575 Web Site: <http://www.cf-chemical.com.tw>

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

Tel: 886-3-3868383 ~5 Fax: 886-3-3869476 E-mail: cheng.fong@msa.hinet.net**CERTIFICATE OF ANALYSIS**

Version: 01

Product name: Procainamide Hydrochloride		
Lot No.: 81102	According to: EP	
Manufacturing Date: 2018/11/15	Retest Date: 2023/11/15	Issued Date: 2019/05/17
Items	Specification	Results
Characters (A) Appearance	A white or very slightly yellow, crystalline powder, hygroscopic.	A white crystalline powder.
(B) Solubility	Very soluble in water, freely soluble in alcohol, slightly soluble in acetone.	Conform
Identification (A). Melting point	166 °C to 170 °C	168.4°C
(B). IR	Accord with the standard spectrum.	Conform
(C). Test of chlorides	Meets the requirements.	Conform
Appearance of solution	Solution S is clear and not more intensely coloured than reference solution B6.	Conform
pH	5.6 ~ 6.3	5.72
Related substances (TLC)	Individual impurity : NMT 0.5%.	Conform
Loss on drying	NMT 0.5%	0.04%
Sulfated ash	NMT 0.1%	0.01%



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Items	Specification	Results
Assay	98.0% ~ 101.0%	100.43%
Residual solvent (1) Methanol	NMT 3000 ppm	18.6 ppm
(2) Toluene	NMT 890 ppm	< LOD
Limit of Palladium (SGS)	NMT 10 ppm	2.21 ppm
Remark : EP edition effective from 01/2017:0567		

2019/05/17

for
Q. A. Manager