

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 : NMT0.5%.	Conform
Loss on drying	NMT 0.5%	0.04%
Sulfated ash	NMT 0.1%	0.01%

METAPHARMACEUTICAL

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26/07/2019

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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
Betty Chen for
Q. A. Manager

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