



CHONGQING SOUTHWEST NO.2 PHARMACEUTICAL FACTORY CO., LTD.

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CERTIFICATE OF ANALYSIS

Name: Procaine Hydrochloride Manufacturing Date: 2025.11.23
Batch No.: 2511068 Inspecting Date: 2025.11.25-2026.02.27
Representative Quantity: 503.02kg Retest Date: 2029.11.22
Inspecting Basis: USP2024 Report date: 2026.03.02

Test items		Specification	Test results
Characters		A white or almost white crystalline powder or colourless crystals	A white crystalline powder
Identification	IR	Infrared absorption spectrophotometry accord with the procaine hydrochloride CRS.	Infrared absorption spectrophotometry accord with the procaine hydrochloride CRS.
	Chemistry reaction	Appears a positive reaction	Appears a positive reaction
	Chlorides reaction	It gives reaction of chlorides.	It gives reaction of chlorides.
Melting point		153~158°C	154.0-155.0°C
Chromatographic purity		Any impurity≤0.5%	<0.5%
		Total impurities≤1.0%	<1.0%
Loss on drying		≤1.0%	0.05%
Residue on ignition		≤0.15%	0.04%
Assay		99.0%~101.0% (Calculated on the dried basis)	100.2%
Acidity		≤0.5ml NaOH(0.02mol/L)	0.12ml
Residual Solvents		Methanol≤3000ppm	66ppm
		Ethanol≤5000ppm	226ppm
		Xylene≤2170ppm	Not detected
Bacterial endotoxins		≤0.6EU/mg	<0.6EU/mg
Microbial Limits		TAMC≤1000CFU/g	<10CFU/g
		TYMC≤100CFU/g	<10CFU/g

Conclusion: Conforms to the specifications of USP2024

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