



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

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CERTIFICATE OF ANALYSIS (HUMAN USE)

Name: Procaine Hydrochloride Manufacturing Date: 2022.05.15
Batch No.: 2205004H Inspecting Date: 2022.05.18-2022.05.24
Representative Quantity: 456.84kg Retest Date: 2026.05.14
Inspecting Basis: EP10.0 Report Date: 2022.06.15

Test items		Specifications	Test results
Characters		A white or almost white, crystalline powder or colourless crystals.	A white white crystalline powder
Identification	Melting point	154-158°C	154.0-155.0°C
	IR	Infrared absorption spectrum accord with the procaine hydrochloride CRS.	Infrared absorption spectrum accord with the procaine hydrochloride CRS.
	Chlorides reaction	It gives reaction of chlorides.	It gives reaction of chlorides.
Appearance of solution		Solution S is clear and colourless.	Solution S is clear and colourless.
pH		5.0-6.5	5.6
Related substances(TLC)		Any impurity≤0.05%	<0.05%
Related substances(HPLC)		PNBA≤0.05%	Not detected
		PABA≤0.1%	Not detected
		Any impurity≤0.05%	0.01%
		Total impurity≤0.5%	0.02%
Loss on drying		≤0.5%	0.06%
Sulphated ash		≤0.1%	0.05%
DEAE		≤0.1%	Not detected
Assay (Calculated on the dried basis)		99.0%~101.0%	99.7%
Residual Solvents		Methanol≤3000ppm	137ppm
		Ethanol≤5000ppm	120ppm
		Xylene≤2170ppm	Not detected
Microbial Limits		TAMC≤100CFU/g	<10CFU/g
		TYMC≤100CFU/g	<10CFU/g
Bacterial endotoxins		≤0.6EU/mg	<0.6EU/mg

Conclusion: Conforms to the specifications of EP10.0

Issued by: 陈莉

Reviewed by: 陈莉

Approved by: 吴燕

