



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

Tel/ Fax: 0086-23-63012195

No.555, Lanxi Road, Degan Street, Jiangjin District, Chongqing

CERTIFICATE OF ANALYSIS (HUMAN USE)

Name: Procaine Hydrochloride Manufacturing Date: 2022.10.28
Batch No.: 2210001H Inspecting Date: 2022.10.30-2022.11.05
Representative Quantity: 452.86kg Retest Date: 2026.10.27
Inspecting Basis: EP10.0 Report Date: 2022.11.07

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	154.5/155.0°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	5.8
Related substances(TLC)		Any impurity ≤ 0.05%	<0.05%
Related substances(HPLC)	PMBA ≤ 0.05%		Not detected
	PABA ≤ 0.1%		Not detected
	Any impurity ≤ 0.05%		0.01%
	Total impurity ≤ 0.5%		0.01%
Loss on drying		≤ 0.5%	0.06%
Sulphated ash		≤ 0.1%	0.04%
DEAE		≤ 0.1%	Not detected
Assay (Calculated on the dried basis)		99.0%-101.0%	100.0%
Residual Solvents	Methanol ≤ 3000ppm		50ppm
	Ethanol ≤ 5000ppm		113ppm
	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: 高恒

Reviewed by: 王华

Approved by: 吴燕

