

F&A PHARMA



QA-0022-R02

**Shandong Chenghui Shuangda
Pharmaceutical Co., Ltd.**

 Address: Economic Development Zone ,Pingyuan County,
Dezhou City, Shandong Province, China

Rev.01 (23.03.01)

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Certificate of Analysis

23/02/2024

Request No.: 003231201

Report No.: 2312103

Product name	Tetracaine hydrochloride			Batch No.	003231201		
Size	25kg/barrel			Package	Cardboard bucket		
Basis	QS-1125&EP11.0			Production unit	Shandong Chenghui Shuangda Pharmaceutical Co., Ltd.		
Quantity	199.48kg	MFG.Date	23.12.19	Request date	23.12.21		
Sampling Date	23.12.21	Report Date	23.12.30	Retest period	36 months	Retest date	2026.11.

Check Item		Standard Regulation	Test Result	Single Judgement
Appearance	Appearance	white or almost white, slightly hygroscopic, crystalline powder.	white, slightly hygroscopic, crystalline powder.	Complies
	Solubility	Freely soluble in water, soluble in ethanol (96%), practically insoluble in heptane.	Freely soluble in water, soluble in ethanol (96%), practically insoluble in heptane.	Complies
	Melting point	134°C ~ 150°C.	147°C ~ 149°C	Complies
Identification	Melting point Identification	It melts at About 131°C.	130°C ~ 131°C	Complies
	Color reaction	To about 5mg add 0.5mL of fuming nitric acid R. Evaporate to dryness on a water-bath, allow to cool and dissolve the residue in 5mL of acetone R. Add 1mL of 0.1M alcoholic potassium hydroxide. A violet colour develops.	Complies	Complies
	Infrared absorption	The infrared absorption spectrum of the sample shall be consistent with that of the reference substance	Complies	Complies
	Chloride identification	It gives reaction (a) of chlorides	Complies	Complies
Analysis	pH	4.5 ~ 6.5	5.6	Complies
	Appearance of solution	The solution should be clear and colorless.	The solution is clear and colorless.	Complies
	Loss on drying	NMT 1.0%	0.19%	Complies
	Sulfated ash	NMT 0.1%.	0.04%	Complies
	Related substances	Impurity A: NMT 0.05%	Not detected	Complies
		Impurity B: NMT 0.1%	0.0006%	
		Impurity C: NMT 0.1%	Not detected	
		Unspecified single impurity: NMT 0.10%	Less than limits of ignored	
	Total impurities: NMT 0.2%		0.0006%	


Certificate of Analysis

Product name	Tetracaine hydrochloride	Batch No.	003231201
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Check Item		Standard Regulation	Test Result	Single Judgement
Analysis	Residual solvents	Ethanol:NMT 5000ppm(LOD 20ppm)	156.6ppm	Complies
		Acetone:NMT 5000ppm(LOD 10ppm)	Not detected	
		N-butanol:NMT 5000ppm(LOD 100ppm)	Not detected	
		Toluene:NMT 890ppm(LOD 9.1ppm)	Not detected	
	N,N-Dimethyle thanolamine	NMT 500ppm(LOD 2.7ppm)	Less than LOD	Complies
	N-butyraldehyde	NMT 30ppm(LOD 0.16ppm)	1.7ppm	Complies
Bacterial endotoxin		Less than 0.15EU/mg	Complies	Complies
Microbiological		TAMC:NMT 10^3 cfu/g	Less than 25×10^1 cfu/g	Complies
		TYMC:NMT 10^2 cfu/g	Less than 10cfu/g	
		Escherichia coli absent in 1 g	Not detected/g	
Assay		NLT 99.0% and NMT 101.0%, calculated on the dried basis.	100.4%	Complies
【Related substances】: Limits of ignored: Chromatographic peaks smaller than the peak area of tetracaine in the sensitivity solution are ignored.				

山东诚汇双达药业有限公司

专用章

Conclusion: Meets the requirements of QS-1125&EP11.0.

Quality Manager:

 超隋
印海
