

JIANGSU JUMPCAN PHARMACEUTICAL CO LTD

Add: Baotawan Daqing west Road Taixing China

CERTIFICATE OF ANALYSIS

正
ORIGINAL

Product	: PRILOCAINE BASE	Batch NO:14083107
Re-issuing Date:	: 2015.05.13	Mfg. Date : 2014.08.31
Approval Date	: 2014.08.31	Exp. Date : 2017.08.30
Tests	Results	Specifications
Appearance	white, crystalline powder	A white or almost white, crystalline powder
Solubility	Complies	Slightly soluble in water, very soluble in acetone and in alcohol
Identification	36.7℃~38.3℃	Melting point: 36℃~39℃
	Complies	By IR, to match with the working standard
	Complies	By TLC, to match with the working standard
TEST		
Optical rotation	0°	-0.10°~+0.10°
O-Toluidine	Meets test	≤100ppm
Related substances	Absent	Impurities B≤0.01%
	Absent	Impurities G≤0.01%
	0.07%	individual unspecified impurities: ≤0.10%
	0.14%	Total impurities≤0.2%
Heavy metals	10ppm	≤ 20 ppm
Sulphated ash	0.07%	≤0.1%
Water	0.04%	≤0.5%
Assay	99.94%	99.0%~101.0%
Conclusion : The product meets the specification of EP8.3		

Analyst

李三华

QC Manager

王波

QA Manager

江苏济川制药有限公司
JIANGSU JUMPCAN PHARMACEUTICAL CO., LTD.

孙强