



西安菲斯弗生物科技有限公司

Xi'an Faithful Biological Technology Co., Ltd.

Certificate of Analysis-Ropivacaine hydrochloride

CAS: 132112-35-7

Batch Number: FTF0240318 **Batch Quantity:** 160kg

Manufacture Date: Mar.16th,2024 **Analysis Date:**Mar.17th,2024 **Certificate Date:** Mar.18th,2024

Storage Store in cool & dry place. Store in well-closed containers.
Shelf life 3 years when properly stored.

Item	Specification	Results
Appearance	White powder	Complies
Identification	(1)it should be positive reaction.	Complies
	(2)ir:meets the requirement.	Complies
Color	the absorbance at 405nm is not more than 0.030.	Complies
	the absorbance at 436nm is not more than 0.025.	
Clarity	meets the requirement.	Complies
PH	4.5~6.0	5.0
Related Substances	total impurity≤0.5%	0.10%
	single impurity≤0.1%	0.05%
	bupivacaine≤0.2%	n.d
Optical Isomers	not more than0.5%	0.04%
Water	5.0%~6.0%	5.3%
Heavy Metals	not more than0.001%	Complies
2,6-dimethylaniline	not more than10ppm	1ppm
Specific rotation	obtain readings at 365 nm: between -210°— -255°	-246°
Assay	98.5%~101.0%	99.40%

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 **INSPECTOR:** 黄子烨

