



福建福瑞明德药业有限公司
FUJIAN FREEMIND PHARM CO., LTD

质量分析报告

Certificate of Analysis

SOR-QS-A05-01

Product:	Tetrahydrozoline hydrochloride	
CAS No.:	522-48-5	
Batch No,	A05-2110001	
Manuf.Date:	2021/10/09	
Retest Date:	2023/09	
Specification:	USP 39	
Item	Standard	Result
Description	White to off-white powder	Conforms
Identification(A,B,C):		
A-IR spectrum	A.S.	Conforms
B-UV spectrum	A.S.	Conforms
C-reaction of chlorides	Positive	Positive
Heavy metals(USP)	NMT 0.005%	<0.005%
Loss on drying(USP)	NMT 1.0%	0.2%
Residue on ignition	NMT 0.1%	<0.1%
Related substances-sum:		
-TLC(USP)	NMT 2.0%	<2.0%
-HPLC	NMT 1.0%	0.8%
Assay(in the dried substance):		
-titration(USP)	98.0-100.5%	99.8%
Residual solvents:		
-Methanol	NMT 3000ppm	Not detected
-Ethanol	NMT 5000ppm	Conforms
-Acetonitrile	NMT 410ppm	Not detected
-Toluene	NMT 890ppm	Not detected
CONCLUSION:	MEETS TO USP 39	
STORAGE:	Airtightness	

Approved: Ren Jianqiang

Checker: Qi Zhentao

Analyst: Wang Lu