

## 杭州凌禾医药科技有限公司

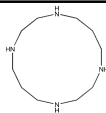
### Hangzhou Linghe Medical Technology Co.,Ltd.

Adds: Room 5760, 5th Floor, Building 1, No. 200, Binwen Road, Changhe Street, Binjiang District, Hangzhou, Zhejiang

Website: www.linghepharm.com E-mail: sales@linghepharm.com

## 产品检验报告单

# Certificate of Analysis

PRODUCT 品名	1,4,8,11-Tetraazacyclotetradecane	STANDARD 检验依据	Enterprise Standard 企标
BATCH NO. 批号	HZKH002-221201	WEIGHT 净重	10.0kg
MANUFACTURING DATE 生产日期	Jun.12, 2022	RETEST DATE 复验期	Jun. 2023
ANALYSIS DATE 检验日期	Jun.13, 2022	REPORT DATE 报告日期	Jun.13, 2022
Structure 结构式		CAS No. CAS 号	295-37-4
Storage 储存	Keep it sealed in a cool place away from light 阴凉处密封避光保存		
TEST ITEM 检测项目	SPECIFICATION LIMITS 检验依据	TEST RESULTS 检验结果	
Character 性状	White needle-like crystalline solids 类白色针状结晶固体	Conforms 合格	
Identification 鉴别	The IR spectrum of sample should be concordant with IR spectrum working standard. 本品的红外光吸收图谱应与对照品的图谱一致。	Conforms 合格	
	The retention time of the major peak in the chromatogram of the test solution corresponds to that of the standard solution as obtained in the assay.含量测定项下供试品溶液的主峰保留时间应与对照品溶液的主峰保留时间一致。	Conforms 合格	
	H-NMR Conforms with structure 符合结构要求	Conforms 合格	
Water (K.F) 水分	≤0.5%	0.15%	
Residue on ignition 炽灼残渣	≤0.1%	0.05%	
Heavy metal 重金属	≤20ppm	Conforms 合格	
Melting point 熔点	187°C-193°C	189.3-191.7°C	
Related substances 有关物质	impurity 杂质 A ≤0.05%	N.D	
	impurity 杂质 B ≤0.05%	N.D	

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	impurity 杂质 $C \leq 0.05\%$	N.D
	Single unknown impurity 单一未知杂质 $\leq 0.05\%$	0.01%
	Total impurities 总杂 $\leq 0.5\%$	0.02%
Assay (HPLC) (on dried basis) 含量 (按干品计)	98.0%-102.0%	100.3%
TEST ITEM 检测项目	SPECIFICATION LIMITS 检验依据	TEST RESULTS 检验结果
XRD	Polymorph Form A	Conforms 合格
Particle size 粒径	D10 $\leq 8\mu\text{m}$ ; D50 $\leq 30\mu\text{m}$ ; D90 $\leq 45\mu\text{m}$ ;	Conforms 合格 Conforms 合格 Conforms 合格
Residual Solvents 溶剂残留	Methanol 甲醇 $\leq 3000\text{ppm}$	86ppm
	Acetonitrile 乙腈 $\leq 410\text{ppm}$	N.D
	Ethyl acetate 乙酸乙酯 $\leq 5000\text{ppm}$	N.D
	Toluene 甲苯 $\leq 890\text{ppm}$	7ppm
	Benzene 苯 $\leq 2\text{ppm}$	N.D
	DMF N,N 二甲基甲酰胺 $\leq 880\text{ppm}$	N.D
	Chlorobenzene 氯苯 $\leq 360\text{ppm}$	N.D
	Ethanol 乙醇 $\leq 5000\text{ppm}$	12ppm
	Acetone 丙酮 $\leq 5000\text{ppm}$	217ppm
	MTBE 甲基叔丁基醚 $\leq 5000\text{ppm}$	N.D
Results: The commodity meets the standard of the Enterprise Standard. 结论: 本品经检验符合企业标准		
Reporter: Caoyi	Checker: XiaZekuan	Reviewer: Caoyi