

CERTIFICATE OF ANALYSIS

API 成品检验报告书

Product Name: 产品名称:		Linagliptin 利格列汀	Batch No.: 产品批号:	LGLT-202309102
Code: 代号:		LGLT	Manufacturing Date: 生产日期:	2023.09.06
Expiry Date/Retest Date: 有效期/复验期:		N/A/2025.09.05	Batch Size: 批量:	29.62kg
Packing Size: 包装规格:		10.00kg/piece 10.00kg/件	Test Method: 检验依据:	SPC-LGLT-01 4.0
Test Items 检测项目		Acceptance Criteria 可接受标准	Results 结果	Conclusions 各项结论
Appearance 性状		White to faint yellow powder. 白色至淡黄色固体	Light yellow powder 浅黄色固体	Conforms 符合规定
Identification 鉴别	IR 红外吸收	The IR spectrum of the sample should be concordant with that of the reference standard. 供试品的红外图谱应与对照品的红外图谱一致	The IR spectrum of the sample is concordant with that of the reference standard. 供试品的红外图谱与对照品的红外图谱一致	Conforms 符合规定
	HPLC 液相色谱	The retention time of the major peak of the reference solution should be concordant with that of the system suitability solution as obtained in enantiomer. 对映异构体测定项下, 对照溶液中主峰保留时间应与系统适用性溶液中主峰的保留时间一致	The retention time of the major peak of the reference solution is concordant with that of the system suitability solution as obtained in enantiomer. 对映异构体测定项下, 对照溶液中主峰保留时间与系统适用性溶液中主峰的保留时间一致	Conforms 符合规定
Water 水分		≤1.0%	0.6%	Conforms 符合规定
Residue on ignition 炽灼残渣		≤0.1%	0.01%	Conforms 符合规定
Enantiomer (S-Linagliptin) 对映异构体(S-利格列汀)		≤0.15%	Not detected 未检出	Conforms 符合规定
Assay 含量		98.0%~102.0% (on the anhydrous basis) 98.0%~102.0% (以无水物计)	100.2%	Conforms 符合规定
Particle size 粒径	D (10)	≤4μm	1μm	Conforms 符合规定
	D (50)	4-15μm	8μm	Conforms 符合规定
	D (90)	≥11μm	26μm	Conforms 符合规定
Related substances 有关物质	Impurity B 杂质 B	≤0.15%	<0.05%	Conforms 符合规定
	Any other impurity 其他任一单杂	≤0.10%	<0.05%	Conforms 符合规定
	Total impurities 总杂	≤1.0%	0.11%	Conforms 符合规定
Reporting limit/报告限: 0.05%				

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Test Items 检测项目		Acceptance Criteria 可接受标准		Results 结果		Conclusions 各项结论	
Residual solvents 溶剂残留		Ethanol 乙醇	≤5000ppm LOQ: 503ppm	<LOQ		Conforms 符合规定	
		Dichloromethane 二氯甲烷	≤600ppm LOQ: 62ppm	Not detected 未检出		Conforms 符合规定	
		△ Toluene △ 甲苯	≤890ppm LOQ: 90ppm	—		—	
		△ N-methyl pyrrolidone △ N-甲基吡咯烷酮	≤530ppm LOQ: 52.69ppm	—		—	
		△ N,N-dimethyl formamide △ N,N-二甲基甲酰胺	≤880ppm LOQ: 88.34ppm	—		—	
		△ Benzene △ 苯	≤2ppm LOQ: 0.99ppm	—		—	
△ Microbiological examination △ 微生物		TAMC 需氧菌总数	≤10 ³ cfu/g	—		—	
		TYMC 霉菌、酵母菌总数	≤10 ² cfu/g	—		—	
		Absence of Escherichia coli (1g) 大肠埃希菌每 1g 应不得检出		—		—	
<p>Remarks: The items with "△" are skipping tests and performed three batches annually. The analytical results are indexed to S230913004, except for Particle size, Identification(HPLC) and Enantiomer(S-Linagliptin).</p> <p>备注: 带"△"为抽检项目, 每年检测三批。除粒径、鉴别(液相色谱)和对映异构体(S-利格列汀)外, 其他检验结果索引 S230913004。</p> <p>Conclusion: The results of the above items meet the requirements of SPC-LGLT-01(KOR) version 4.0.</p> <p>结论: 本品上述项目检测结果符合 SPC-LGLT-01 (韩国方向) 质量标准 4.0 版规定。</p>							

Reported by/Date: 报告人/日期:	王会英/2023.09.26	Reviewed by/Date: 审核人/日期:	苏利霞/2023.09.26
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