BeiGene

Certificate of Analysis
分析证书

Certificate of Analysis for BGB-16673 Drug Substance-US

Document No.: VV-QDOC-211149 Version: 1.0, Effective Date: 10 Dec 2024

Report ID 报告编号: VV-QDOC-256244
Ver. No.版本号: 1.0

Product Name **产品名称**	BGB-16673 Drug Substance	**Material No.** **物料号**	N/A
Batch No. **批号**	CM-C200727003-FPF25101	**Storage Conditions** **贮存条件**	NMT 25℃, double LDPE bags, tied separately with a cable-tie, enclosed in foil bag and then put into HDPE Drum
Date of Manufacture **生产日期**	2025.03.29	**Retest Date** **复验期**	2027.09.28
Manufacturer **生产商**	Changzhou SynTheAll Pharmaceutical Co., Ltd.	**Report Date** **报告日期**	See Veeva Electronic Signature

Testing Items **测试项目**	**Acceptance Criteria** **接受标准**	**Results** **检测结果**	**Conclusion** **结论**
Appearance (Visual Examination)	Light yellow to yellow powder	Yellow powder	Pass
Identification (Infrared Spectroscopy IR, USP<197>)	Conforms to reference standard	Conforms to reference standard	Pass
Identification (LC)	Conforms to reference standard	Conforms to reference standard	Pass
Polymorphic form (XRPD, USP<197>)	Conforms to reference standard	Conforms to reference standard	Pass
Assay (on anhydrous basis) (LC)	98.0% – 102.0%	100.3%	Pass
Related substances (LC)			
BGB-24860	≤ 0.30%	<0.05%	Pass
BGB-23578	≤ 0.30%	<0.05%	Pass
BG-81785a	≤ 0.20%	<0.05%	Pass
BG-81785b	≤ 0.20%	<0.05%	Pass
Single unspecified impurity	≤ 0.10%	<0.05%	Pass
Total impurities	≤ 1.5%	<0.05%	Pass
Residual 16673-Z4 (LC)	≤ 0.20%	0.05%	Pass

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Testing Items 测试项目	Acceptance Criteria 接受标准	Results 检测结果	Conclusion 结论
Residual solvents (GC)			
Methanol	≤ 3000 ppm	none detected	Pass
Dichloromethane	≤ 600 ppm	none detected	Pass
Tetrahydrofuran	≤ 720 ppm	none detected	Pass
Ethyl acetate	≤ 5000 ppm	1951 ppm	Pass
Isopropanol	≤ 5000 ppm	none detected	Pass
Water content (Karl Fischer coulometric titration method, USP<921>)	≤ 2.5%	0.4%	Pass
Residue on ignition (USP<281>)	≤ 0.2%	0.0%	Pass
Particle size distribution (Laser diffraction method)	D_{90}≤15µm	8µm	Pass

Conclusion 结论：
CoA was issued against US clinical specification VV-QDOC-55984 version 4.0, and the results met the requirements of the specification.

Note备注：
N/A

Prepared By /Date 撰写人/日期	Reviewed By /Date 复核人/日期	Approved By /Date 批准人/日期
See Veeva Electronic Signature 见 Veeva系统电子签名	See Veeva Electronic Signature 见 Veeva系统电子签名	See Veeva Electronic Signature 见 Veeva系统电子签名

修订历史/Revision History

版本号 Version	变更概述 Brief description of Change
1.0	Newly established.

Document Approvals

Approved Date: 14 May 2025

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