



 BeiGene	Certificate of Analysis	1 of 2
BGB-16673 Drug Substance-US		

Batch No.:	CR-C200727003-FPF24004	Manufactured By:	Changzhou SynTheAll Pharmaceutical Co., Ltd.
Manufacture Date:	2024.06.13	Retest Date:	2026.12.12
Specification:	VV-QDOC-55984 version 3.0		
Storage Conditions:	NMT 25°C		

TEST ITEM	METHOD	ACCEPTANCE CRITERIA	RESULTS
Appearance	Visual Examination	Light yellow to yellow powder	Yellow powder
Identification	Infrared Spectroscopy (IR) USP<197>	Conforms to reference standard	Conforms to reference standard
	HPLC	Conforms to reference standard	Conforms to reference standard
Polymorphic form	XRPD USP<941>	Conforms to reference standard	Conforms to reference standard
Assay (Anhydrous basis)	HPLC	97.0% – 103.0%	100.8%
Single unspecified impurity	HPLC	NMT 0.30%	RRT 0.83: 0.06%
Total impurities		NMT 2.0%	0.06%
Residual solvents	GC		
Methanol		NMT 3000 ppm	none detected
Dichloromethane		NMT 600 ppm	none detected
Tetrahydrofuran		NMT 720 ppm	none detected
Ethyl acetate		NMT 5000 ppm	1825 ppm
Isopropanol		NMT 5000 ppm	none detected
Enantiomeric impurity (BGB-21764)	HPLC	NMT 0.5%	<0.10%

 BeiGene	Certificate of Analysis	2 of 2
BGB-16673 Drug Substance-US		

TEST ITEM	METHOD	ACCEPTANCE CRITERIA	RESULTS
Water Content	Karl Fischer coulometric titration method USP <921>	NMT 3.5%	0.42%
Residue on ignition	ROI USP <281>	NMT 0.2%	0.0%
Elemental impurities (Pd)	ICP-MS	NMT 25 ppm	<3 ppm

Conclusion: CoA was issued against US Regulatory specification VV-QDOC-55984 version 3.0, and the results met the requirements of the specification.		
Note: Newly established.		
Prepared by:		
Title	Name	Signature/date
Senior Data Review Specialist, Global QC, Project and Technology	Yanfang Liu	<div>DocuSigned by:  签名者名称: Yanfang Liu 签名原因: 我是此文档的作者 签名时间: 05-Jul-2024 09:38:27 CST 7203F3A3565F49D49A28CEA09CA77C4A</div>
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Title	Name	Signature/date
Manager, Global QC, Project and Technology	Yanjun Xia	<div>DocuSigned by:  Signer Name: Kathy Xia Signing Reason: I have reviewed this document Signing Time: 05-Jul-2024 10:13:28 CST C6B4663213B145F9BB3762F5A20A1AFD</div>
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Associate QA Manager, Clinical Small Molecule	Gang Wang	<div>DocuSigned by:  Signer Name: Gang Wang Signing Reason: I approve this document Signing Time: 05-Jul-2024 10:39:50 CST 95CE129A73E84B393049636C558C1F2</div>