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

Batch No.:	CR-C200727003-FPF24002	Manufactured By:	Changzhou SynTheAll Pharmaceutical Co., Ltd.
Manufacture Date:	2024.05.18	Retest Date:	2026.11.17
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%	100.2%
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	<500 ppm
Isopropanol		NMT 5000 ppm	none detected
Enantiomeric impurity (BGB-21764)	HPLC	NMT 0.5%	<0.10%

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TEST ITEM	METHOD	ACCEPTANCE CRITERIA	RESULTS
Water Content	Karl Fischer coulometric titration method USP <921>	NMT 3.5%	0.53%
Residue on ignition	ROI USP <281>	NMT 0.2%	0.1%
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: <i>Yanfang Liu</i> Signature Name: Yanfang Liu Signature Reason: 我是此文档的作者 Signature Time: 13-Jun-2024 18:37:22 CST 7203F3A3565F49D49A28CEA09CA77C4A</div>
Reviewed by:		
Title	Name	Signature/date
Manager, Global QC, Project and Technology	Yanjun Xia	<div>DocuSigned by: <i>Kathy Xia</i> Signature Name: Kathy Xia Signature Reason: I have reviewed this document Signature Time: 14-Jun-2024 10:35:57 CST C6B4663213B145F9BB3762F5A20A1AFD</div>
Approved By:		
Title	Name	Signature/date
Associate QA Manager, Clinical Small Molecule	Gang Wang	<div>DocuSigned by: <i>Gang Wang</i> Signature Name: Gang Wang Signature Reason: I approve this document Signature Time: 14-Jun-2024 11:10:26 CST 95CE129A73E84BB393049636C558C1F2</div>