




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

Batch No.:	CR-C200727003-FPF24001	Manufactured By:	Changzhou SynTheAll Pharmaceutical Co., Ltd.
Manufacture Date:	2024.01.11	Expiry Date:	2026.07.10
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%	99.7%
Single unspecified impurity	HPLC	NMT 0.30%	RRT 0.83: 0.07% RRT 0.84:0.05%
Total impurities		NMT 2.0%	0.11%
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%	none detected

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

TEST ITEM	METHOD	ACCEPTANCE CRITERIA	RESULTS
Water Content	Karl Fischer coulometric titration method USP <921>	NMT 3.5%	0.45%
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
GMP QC Senior Data Review Specialist GMP QC	Yanfang Liu	 <small>DocuSigned by: Yanfang Liu 签名者名称: Yanfang Liu 签名原因: 我是此文档的作者 签名时间: 29-Jan-2024 11:16:15 CST 7203F3A3565F49D49A28CEA09CA77C4A</small>
Reviewed by:		
Title	Name	Signature/date
Manager Global QC	Yanjun Xia	 <small>DocuSigned by: Kathy Xia 签名者名称: Kathy Xia 签名原因: I have reviewed this document 签名时间: 29-Jan-2024 11:30:27 CST C6B4663213B145F98B3762F5A20A1AFD</small>
Approved By:		
Title	Name	Signature/date
Associate Manager, GMP QA	Gang Wang	 <small>DocuSigned by: Gang Wang 签名者名称: Gang Wang 签名原因: I approve this document 签名时间: 29-Jan-2024 12:04:20 CST 95CE129A73E84BB393049636C558C1F2</small>