
 <b>BeiGene</b>	<b>Certificate of Analysis</b>	<b>1 of 2</b>
<b>BGB-16673 Drug Substance-US</b>		

Batch No.:	CR-C200727003-FPF24003	Manufactured By:	Changzhou SynTheAll Pharmaceutical Co., Ltd.
Manufacture Date:	2024.06.09	Retest Date:	2026.12.08
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%	101.0%
Single unspecified impurity	HPLC	NMT 0.30%	RRT 0.83: 0.07%
Total impurities		NMT 2.0%	0.07%
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	1203 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%	0.35%
Residue on ignition	ROI USP <281>	NMT 0.2%	0.0%
Elemental impurities (Pd)	ICP-MS	NMT 25 ppm	<3 ppm

<b>Conclusion:</b> CoA was issued against US Regulatory specification VV-QDOC-55984 version 3.0, and the results met the requirements of the specification.		
<b>Note:</b> Newly established.		
<b>Prepared by:</b>		
<b>Title</b>	<b>Name</b>	<b>Signature/date</b>
Senior Data Review Specialist, Global QC, Project and Technology	Yanfang Liu	<div>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: 05-Jul-2024   09:38:14 CST 7203F3A3565F49D49A28CEA09CA77C4A</div>
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