



浙江九洲药业股份有限公司

ZHEJIANG JIUZHOU PHARMACEUTICAL CO., LTD.

地址: 浙江省台州市椒江区外沙路99号 邮编: 318000

Address: WAISHA ROAD 99, JIQUAN TAIZHOU CITY, ZHEJIANG, CHINA 318000

Tel: 0086 576 88827187 Fax: 0086 576 88827187 E-mail: compliance@jiuzhoupharma.com

WQTP-SPR-2001-02 5.0(2022-10-31)

检验报告单
CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平CARBAMAZEPINE

代号Code.: 2001-0004

批号BATCH No.	200100A250103	标准 SPECIFICATION	USP
包装PACKAGE	25.00kg/桶 drum,52桶 drums	生产日期MAFG DATE	2024-12
数量QUANTITY	1300.00 kg	复验日期RETEST DATE	2028-11

指标名称Test		技术要求 Requirement	结果Results
外观Appearance		白色至类白色粉末 White to Off-white Powder	白色粉末 White Powder
鉴别 Identification	A.红外吸收光谱IR	与对照品图谱一致 Corresponding to the spectrum of reference standard	与对照品图谱一致 Corresponding to the spectrum of reference standard
	B.超高效液相色谱UPLC	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard
X射线衍射光谱X-ray Diffraction		与对照图谱一致 Corresponding to Reference Spectrum	与对照图谱一致 Corresponding to Reference Spectrum
酸度Acidity		$\leq 1.0\text{mL/g}$ (0.010mol/L NaOH)	符合规定 Conform With
碱度Alkalinity		$\leq 1.0\text{mL/g}$ (0.010mol/L HCl)	符合规定 Conform With
干燥失重Loss on Drying		$\leq 0.5\%$	0.05 %
炽灼残渣Residue on Ignition		$\leq 0.1\%$	<0.05 %
氯化物Chlorides		$\leq 0.014\%$	<0.014 %
有关物质 /UPLC Related Compounds	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	$\leq 0.2\%$	<0.05 %
	杂质B (亚氨基苄) Iminostilbene	$\leq 0.2\%$	<0.05 %
	其它单个杂质Any Other Impurity	$\leq 0.2\%$	<0.05 %
	总杂质Total Impurities	$\leq 0.5\%$	<0.05 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0~102.0%	99.8 %
残留溶剂/HS-GC Residual Solvents	甲醇Methanol	$\leq 3000\text{ppm}$	<300 ppm
	乙醇Ethanol	$\leq 5000\text{ppm}$	<500 ppm
	氯苯Chlorobenzene	$\leq 360\text{ppm}$	<36 ppm
DocId: GUID-F7682879-7EF1-4B54-A68B-8EBFD365B0AA_5_en-US			
结论 CONCLUSION	本品符合 USP 标准规定 COMFORM WITH USP		

制作者/日期 PREPARED BY/DATE	2025.01.07	复核者/日期 QC MANAGER/DATE	2025.01.07	批准人/日期 QA APPROVER /DATE	2025.01.07
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批号 BATCH No.		200100A250103	
包装 PACKAGE	25.00kg/桶 drum,52桶 drums	生产日期 MAFG DATE	2024-12
数量 QUANTITY	1300.00 kg	复验日期 RETEST DATE	2028-11

说明 Notes	颗粒度符合80目筛网过筛工艺 Particle size conform with 80 mesh sieving process
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制作者/日期 PREPARED BY/DATE	2025.01.07	复核者/日期 QC MANAGER/DATE	2025.01.07	批准人/日期 QA APPROVER /DATE	2025.01.07
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检验报告单 CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平 CARBAMAZEPINE

代号 Code.: 2001-0004

批号 BATCH No.	200100A241256	标准 SPECIFICATION	USP
包装 PACKAGE	25.00kg/桶 drum, 52桶 drums 12.10kg/桶 drum, 1桶 drum	生产日期 MAFG DATE	2024-12
数量 QUANTITY	1312.10 kg	复验日期 RETEST DATE	2028-11

指标名称 Test		技术要求 Requirement	结果 Results
外观 Appearance		白色至类白色粉末 White to Off-white Powder	白色粉末 White Powder
鉴别 Identification	A. 红外吸收光谱 IR	与对照品图谱一致 Corresponding to the spectrum of reference standard	与对照品图谱一致 Corresponding to the spectrum of reference standard
	B. 超高效液相色谱 UPLC	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard
X射线衍射光谱 X-ray Diffraction		与对照图谱一致 Corresponding to Reference Spectrum	与对照图谱一致 Corresponding to Reference Spectrum
酸度 Acidity		$\leq 1.0\text{mL/g}$ (0.010mol/L NaOH)	符合规定 Conform With
碱度 Alkalinity		$\leq 1.0\text{mL/g}$ (0.010mol/L HCl)	符合规定 Conform With
干燥失重 Loss on Drying		$\leq 0.5\%$	0.05 %
炽灼残渣 Residue on Ignition		$\leq 0.1\%$	<0.05 %
氯化物 Chlorides		$\leq 0.014\%$	<0.014 %
有关物质 /UPLC Related Compounds	杂质 A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	$\leq 0.2\%$	<0.05 %
	杂质 B (亚氨基) Iminostilbene	$\leq 0.2\%$	<0.05 %
	其它单个杂质 Any Other Impurity	$\leq 0.2\%$	<0.05 %
	总杂质 Total Impurities	$\leq 0.5\%$	<0.05 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0-102.0%	99.3 %
残留溶剂/HS-GC Residual Solvents	甲醇 Methanol	$\leq 3000\text{ppm}$	<300 ppm
	乙醇 Ethanol	$\leq 5000\text{ppm}$	<500 ppm
	氯苯 Chlorobenzene	$\leq 360\text{ppm}$	<36 ppm
DocId: GUID-F7682879-7EF1-4B54-A68B-8EBFD365B0AA_5_en-US			
结论 CONCLUSION	本品符合 USP 标准规定 CONFORM WITH USP		

制作者/日期 PREPARED BY/DATE	<i>Ex 2024.12.31</i>	复核者/日期 QC MANAGER/DATE	<i>31 2024.12.31</i>	批准人/日期 QA APPROVER /DATE	<i>2024.12.31</i>
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品名 PRODUCT: 卡马西平 CARBAMAZEPINE

批号 BATCH No.		200100A241256	
包装 PACKAGE	25.00kg/桶 drum, 52桶 drums 12.10kg/桶 drum, 1桶 drum	生产日期 MAFG DATE	2024-12
数量 QUANTITY	1312.10 kg	复验日期 RETEST DATE	2028-11

说明 Notes	颗粒度符合80目筛网过筛工艺 Particle size conform with 80 mesh sieving process
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制作者/日期 PREPARED BY/DATE	<i>L. Wang</i> 2024.12.31	复核者/日期 QC MANAGER/DATE	<i>L. Wang</i> 2024.12.31	批准人/日期 QA APPROVER /DATE	<i>M. Wang</i> 2024.12.31
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品名 PRODUCT: 卡马西平CARBAMAZEPINE

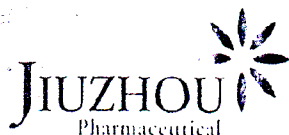
代号Code.: 2001-0004

批号BATCH No.	200100A241255	标准 SPECIFICATION	USP
包装PACKAGE	25.00kg/桶 drum,52桶 drums 13.60kg/桶 drum,1桶 drum	生产日期MAFG DATE	2024-12
数量QUANTITY	1313.60 kg	复验日期RETEST DATE	2028-11

指标名称Test		技术要求 Requirement	结果Results
外观Appearance		白色至类白色粉末 White to Off-white Powder	白色粉末 White Powder
鉴别 Identification	A.红外吸收光谱IR	与对照品图谱一致 Corresponding to the spectrum of reference standard	与对照品图谱一致 Corresponding to the spectrum of reference standard
	B.超高效液相色谱UPLC	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard
X射线衍射光谱X-ray Diffraction		与对照图谱一致 Corresponding to Reference Spectrum	与对照图谱一致 Corresponding to Reference Spectrum
酸度Acidity		$\leq 1.0\text{mL/g}$ (0.010mol/L NaOH)	符合规定 Conform With
碱度Alkalinity		$\leq 1.0\text{mL/g}$ (0.010mol/L HCl)	符合规定 Conform With
干燥失重Loss on Drying		$\leq 0.5\%$	$< 0.05\%$
炽灼残渣Residue on Ignition		$\leq 0.1\%$	$< 0.05\%$
氯化物Chlorides		$\leq 0.014\%$	$< 0.014\%$
有关物质 /UPLC Related Compounds	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	$\leq 0.2\%$	$< 0.05\%$
	杂质B (亚氨基芪) Iminostilbene	$\leq 0.2\%$	$< 0.05\%$
	其它单个杂质Any Other Impurity	$\leq 0.2\%$	0.05 %
	总杂质Total Impurities	$\leq 0.5\%$	0.05 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0~102.0%	98.9 %
残留溶剂/HS-GC Residual Solvents	甲醇Methanol	$\leq 3000\text{ppm}$	$< 300\text{ ppm}$
	乙醇Ethanol	$\leq 5000\text{ppm}$	$< 500\text{ ppm}$
	氯苯Chlorobenzene	$\leq 360\text{ppm}$	$< 36\text{ ppm}$
DocId: GUID-F7682879-7EF1-4B54-A68B-8EBFD365B0AA_5_en-US			
结论 CONCLUSION	本品符合 USP 标准规定 COMFORM WITH USP		

制作者/日期 PREPARED BY/DATE	<i>Le Mei</i> 2024.12.31	复核者/日期 QC MANAGER/DATE	<i>SL</i> 2024.12.31	批准人/日期 QA APPROVER /DATE	<i>Li Mei</i> 2024.12.31
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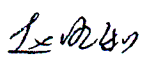
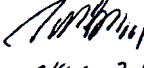
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检验报告单
CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平 CARBAMAZEPINE

批号 BATCH No.		200100A241255	
包装 PACKAGE	25.00kg/桶 drum, 52桶 drums 13.60kg/桶 drum, 1桶 drum	生产日期 MAFG DATE	2024-12
数量 QUANTITY	1313.60 kg	复验日期 RETEST DATE	2028-11

说明 Notes	颗粒度符合80目筛网过筛工艺 Particle size conform with 80 mesh sieving process
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制作者/日期 PREPARED BY/DATE	 2024.12.31	复核者/日期 QC MANAGER/DATE	 2024.12.31	批准人/日期 QA APPROVER/DATE	 2024.12.31
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WQTP-SPR-2001-02 5.0(2022-10-31)

检验报告单 CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平CARBAMAZEPINE

代号Code.: 2001-0004

批号BATCH No.	200100A241254	标准 SPECIFICATION	USP
包装PACKAGE	25.00kg/桶 drum, 52桶 drums 17.04kg/桶 drum, 1桶 drum	生产日期MAFG DATE	2024-12
数量QUANTITY	1317.04 kg	复验日期RETEST DATE	2028-11

指标名称Test		技术要求 Requirement	结果Results
外观Appearance		白色至类白色粉末 White to Off-white Powder ✓	白色粉末 White Powder
鉴别 Identification	A. 红外吸收光谱IR	与对照品图谱一致 Corresponding to the spectrum of reference standard ✓	与对照品图谱一致 Corresponding to the spectrum of reference standard
	B. 超高效液相色谱UPLC	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard ✓	与对照品保留时间一致 Retention time of the sample conforms to that of the reference standard
X射线衍射光谱X-ray Diffraction		与对照图谱一致 Corresponding to Reference Spectrum ✓	与对照图谱一致 Corresponding to Reference Spectrum
酸度Acidity		≤1.0mL/g (0.010mol/L NaOH) ✓	符合规定 Conform With
碱度Alkalinity		≤1.0mL/g (0.010mol/L HCl) ✓	符合规定 Conform With
干燥失重Loss on Drying		≤0.5% ✓	<0.05 %
炽灼残渣Residue on Ignition		≤0.1% ✓	<0.05 %
氯化物Chlorides		≤0.014% ✓	<0.014 %
有关物质 /UPLC Related Compounds	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	≤0.2% ✗	<0.05 %
	杂质B (亚氨基苄) Iminostilbene	≤0.2% ✗	<0.05 %
	其它单个杂质Any Other Impurity	≤0.2% ✗	0.05 %
	总杂质Total Impurities	≤0.5% ✓	0.05 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0~102.0% ✓	99.8 %
残留溶剂/HS-GC Residual Solvents	甲醇Methanol	≤ 3000ppm ✗	<300 ppm
	乙醇Ethanol	≤ 5000ppm ✗	<500 ppm
	氯苯Chlorobenzene	≤ 360ppm ✗	<36 ppm
DocId: GUID-F7682879-7EF1-4B54-A68B-8EBFD365B0AA_5_en-US			
结论 CONCLUSION	本品符合 USP 标准规定 CONFORM WITH USP		

制作者/日期 PREPARED BY/DATE	1801 2025-01.19	复核者/日期 QC MANAGER/DATE	1801 2025.01.20.	批准人/日期 QA APPROVER /DATE	1801 2025-01.20
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CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平 CARBAMAZEPINE

批号 BATCH No.		200100A241254	
包装 PACKAGE	25.00kg/桶 drum, 52桶 drums 17.04kg/桶 drum, 1桶 drum	生产日期 MAFG DATE	2024-12
数量 QUANTITY	1317.04 kg	复验日期 RETEST DATE	2028-11

说明 Notes	颗粒度符合80目筛网过筛工艺 Particle size conform with 80 mesh sieving process
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制作者/日期 PREPARED BY/DATE	潘小奇 2025-01-19	复核者/日期 QC MANAGER/DATE	潘小奇 2025-01-20	批准人/日期 QA APPROVER /DATE	潘小奇 2025-01-20
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