

Bagian: QC

Due Date : 22 Oct 2026

Tanggal : 01 Oct 2026

ANALISA PERMINTAAN BARANG

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IMO10028	Jasa Analisa Difraksi Sinar X standar Carbamazepine	Js	0	4	-4	0	4	0	0

Catatan :

- Jasa untuk pemenuhan pemeriksaan parameter Difraksi Sinar X pada standar Carbamazepine sesuai dengan spesifikasi yang berlaku dan mengacu pada kompedial terkini Farmakope Indonesia , Berikut no batch yang akan diuji :

1. 200100A260631 Ex. Zhejiang Jiuzhou
2. 200100A260632 Ex. Zhejiang Jiuzhou
3. 200100A260633 Ex. Zhejiang Jiuzhou
4. 200100A260634 Ex. Zhejiang Jiuzhou

- Estimasi harga : Rp.650.000/Jasa.

- Pengujian terakhir pada bulan Februari 2026 (PF000232)

Latar Belakang Permintaan

- Pengujian tersebut belum bisa dilakukan secara internal dikarenakan belum terdapat instrumen XRD di PT. Mersifarma.

- Sebagai pemenuhan regulasi dan perilisan pemeriksaan kedatangan bahan baku Carbamazepine.

- Pengujian eksternal dilakukan di PT. Nusa Veritas Inspektama.

Terlampir metode analisa, penawaran harga dan CoA bahan baku.

Dibuat

 01/26
ADA 10

Mengetahui

 01/26
w



METODE PENGUJIAN BAHAN AWAL
RAW MATERIAL ANALYSIS METHOD
CARBAMAZEPINE

Page 3 of 13

PT. MERSIFARMA TM.
DIVISI MANUFACTURING
SUKABUMI-INDONESIA

Document No :
RD-02-MBA/021.02
Valid Date :
January 27th 2023

DEPARTMENT
RESEARCH AND DEVELOPMENT

SECTION
ANALYTICAL DEVELOPMENT

Prepared by :

Checked by :

Approved by :

Ita Aryani

AD Staff

Date : 09/01/23

Reza Aulia Gusli

AD Supervisor

Date : 10/01/23

Rustam Wijaya

R&D Manager

Date : 10/01/23

Selvi

QA Manager

Date : 10/01/23

Changed No :

2RD20/MPBAA/021.01

Date :

December 05th 2016

Perform the test as stated in the Standard Procedure for Using the NanoRam Handheld Raman System that applies at PT. Mersifarma TM.

DIFRAKSI SINAR - X ^(1,2,3)
X-RAY DIFFRACTION

Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku.
Requirements Meets the requirements for raw material specifications
Cara Pemeriksaan :
Procedure

Lakukan pengujian menggunakan Alat Difraktometer.
Perform the test using a diffractometer.

KEASAMAN ^(1,2,3)
ACIDITY

Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku.
Requirements Meets the requirements for raw material specifications

Pembuatan Indikator Phenolphthalein

Preparation Phenolphthalein Indicator

1. Timbang seksama 1.0 g phenolphthalein.
Weight accurately 1.0 g Phenolphthalein
2. Masukkan ke dalam gelas piala 100 mL.
Put in a 100 mL to beaker glass
3. Tambahkan 80 mL ethanol, aduk sampai larut.
Add 80 mL Ethanol, mix until dilute.
4. Tambahkan ethanol sampai 100 mL, aduk sampai homogen.
Add Ethanol until 100 mL, mix until homogeneous.

Pembuatan Natrium Hidroksida (NaOH) 0.01 N

Preparation Sodium Hydroxide (NaOH) 0.01 N

1. Timbang seksama 400.0 mg Natrium Hidroksida (NaOH).
Weight accurately 400.0 mg Sodium Hydroxide (NaOH)
2. Masukkan ke dalam gelas piala 1000 mL.
Put in a 1000 mL to beaker glass.
3. Tambahkan 500 mL air, aduk sampai larut.
Add 500 mL purified water, mix until dilute.
4. Tambahkan air hingga 1000 mL, aduk sampai homogen.
Add purified water up to 1000 mL, mix until homogeneous.

Pembakuan Natrium Hidroksida (NaOH) 0.01 N

Standardization Sodium Hydroxide (NaOH) 0.01 N

1. Timbang seksama 50.0 mg Kalium Hidrogen phthalat (C₈H₅KO₄).
Weight accurately 50.0 mg Potassium Hydrogen Phthalate (C₈H₅KO₄)
2. Masukkan ke dalam erlenmeyer 250 mL.
Put in a 250 mL to Erlenmeyer



LIST PARAMETER BAHAN BAKU BELUM BISA DIKERJAKAN OLEH QC

No.	Parameter	Nama Bahan	Kendala di QC	Keterangan (Bisa/Tidak oleh R&D)
48	Indeks Bias	Isoflurane	Alat refraktometer yang tersedia di lab QC Mersifarma memiliki range pembacaan di 1.30 - 1.70 sedangkan spek perhitungan isoflurane berada di sekitar angka 1.2 sehingga alat tidak mampu <i>support</i> pembacaan	Alat Refractometer hanya tersedia di Lab QC, dan range yang diperlukan pada pengujian tidak masuk dalam range alat refractometer yang tersedia di QC
49	Fase Kristal	Lithium Karbonate	Tidak terdapat instrumen XRD	Tidak terdapat instrumen XRD
50	Difraksi Sinar-X	Carbamazepine	Tidak terdapat instrumen XRD	Tidak terdapat instrumen XRD
51	Residual Solvent (1,4 dioxane, benzene, chloroform, dichloromethane, trichloroethylene)	N-Acetylcysteine	Belum terdapat kolom G27 5 um 0.53 mm x 5 m, belum trial pengembangan metode dan validasi metode oleh RnD	Belum terdapat kolom G27 5 um 0.53 mm x 5 m, belum trial pengembangan metode dan validasi metode
52	Uji Pirogen	RL infus	Pengujian membutuhkan hewan uji kelinci dan di PT. Mersifarma belum tersedia fasilitas ternak dan pengujian untuk kelinci	Pengujian membutuhkan hewan uji kelinci dan di PT. Mersifarma belum tersedia fasilitas ternak dan pengujian untuk kelinci
53	Average Molecular Mass	PEG 6000 dan PEG 400	Belum tersedia reagen. Belum trial pengembangan metode dan validasi metode.	Belum tersedia reagen. Belum trial pengembangan metode dan validasi metode.
54	Etanol	Phenytoin Injeksi/Kutoin Injeksi	Belum tersedia kolom dan belum melakukan pengembangan metode analisis	Belum tersedia kolom dan belum melakukan pengembangan metode analisis
55	Propilenglikol	Phenytoin Injeksi/Kutoin Injeksi	Belum tersedia kolom dan belum melakukan pengembangan metode analisis	
56	Aflatoksin Total (B1, B2, G2, dan G2)	Polygala Tenuifolia Kapsul 100 mg	Belum tersedia instrumen LC-MS/MS, kolom, reagen, dan bahan penunjang lainnya	Belum tersedia instrumen LC-MS/MS, kolom, reagen, dan bahan penunjang lainnya


 50/09/24
 OR

Kepada Yth.
Ibu Julfriaeni La Sabatini Br Bangun
PT. Mersifarma Tirmaku Mercusana
Julfriaeni_Bangun@mersifarma.com

Nomor Penawaran : SPH/NVI/053/12/2025/AV
Tanggal : 22 Desember 2025

Dengan Hormat.

Menjawab permintaan Bapak/Ibu terkait pengujian laboratorium dengan ini kami sampaikan penawaran harga uji sebagai berikut:

NO	JENIS LAYANAN	Jumlah Sampel	Harga	Total Harga
1.	Analysis of X-Ray Diffraction (XRD) analysis	8	Rp. 650.000	Rp. 5.200.000

BIAYA PENGUJIAN (IDR)	
Subtotal	Rp. 5.200.000
PPN	Rp. 572.000
Total	Rp. 5.772.000

Catatan

- *Harga diatas merupakan harga **per-sampelnya**
- *Untuk estimasi lama pengujian adalah **hari kerja (Jam Kerja)** terhitung setelah sampel tiba
- *Jika terdapat kebutuhan tambahan seperti preparasi atau pengolahan sampel khusus biaya akan diinformasikan secara terpisah
- *Mengajukan layanan pengujian melalui website: **elsa.brin.go.id**
- *Informasi lebih lanjut dapat menghubungi: **+62 858-1305-7001**

Demikian penawaran ini kami sampaikan, atas perhatian serta kerjasama yang baik kami mengucapkan terima kasih.

Hormat Kami,
BRIN - PT. Nusa Veritas Inspektama



I Nyoman Kidarma Jaya
Manajer



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, JIAOJIANG, TAIZHOU CITY, ZHEJIANG, CHINA 318000

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

WQTP-SPR-2001-11 1.0(2024-04-11)

检验报告 CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平CARBAMAZEPINE

代号CODE No.: 2001-0018

批号BATCH No.	200100A260631	规格 SPECIFICATION	注册 Register USP
包装PACKAGE	25.00kg/桶 drum, 53桶 drums 10.52kg/桶 drum, 1桶 drum	生产日期MAFG DATE	2026-06
数量QUANTITY	1335.52 kg	复验日期RETEST DATE	2030-05

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 %
有机杂质 /UPLC Organic Impurities	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	≤0.1% ✓	<0.03 %
	杂质B (亚氨基苄) Iminostilbene	≤0.10% ✓	<0.03 %
	其它单个杂质Any Other Impurity	≤0.06% ✓	0.04 %
	总杂质Total Impurities	≤0.5% ✓	0.04 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0~102.0% ✓	100.2 %
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_6_en-US

结论 CONCLUSION	本品符合 注册 USP 标准规定 COMFORM WITH Register USP Standard ✓		
制作者/日期 PREPARED BY/DATE	 2026.07.14	复核者/日期 QC MANAGER/DATE	 2026.07.14
		批准人/日期 QA APPROVER /DATE	 2026.07.14



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, JIAOJIANG, TAIZHOU CITY, ZHEJIANG, CHINA 318000

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

WQTP-SPR-2001-11 1.0(2024-04-11)

检验报告单 CERTIFICATE OF ANALYSIS

代号CODE No.: 2001-0018

品名 PRODUCT: 卡马西平CARBAMAZEPINE

批号BATCH No.	200100A260632	注册 Register USP
包装PACKAGE	25.00kg/桶 drum, 53桶 drums 10.20kg/桶 drum, 1桶 drum	生产日期MAFG DATE 2026-06
数量QUANTITY	1335.20 kg	复验日期RETEST DATE 2030-05

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
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 %
有机杂质 /UPLC Organic Impurities	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	≤0.1% ✓ ≤0.03 %
	杂质B (亚氨基苄) Iminostilbene	≤0.10% ✓ ≤0.03 %
	其它单个杂质Any Other Impurity	≤0.06% ✓ 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% ✓ 99.6 %
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_6_en-US

结论 CONCLUSION	本品符合 注册 USP 标准规定 COMFORM WITH Register USP Standard
------------------	--

制作者/日期 PREPARED BY/DATE	2026.07.14	复核者/日期 QC MANAGER/DATE	2026.07.14	批准人/日期 QA APPROVER /DATE	2026.07.14
-------------------------------	------------	---------------------------	------------	--------------------------------	------------



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, JIAOJIANG, TAIZHOU CITY, ZHEJIANG, CHINA 318000

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

WQTP-SPR-2001-11 1.0(2024-04-11)

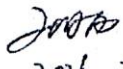
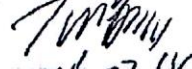
检验报告单
CERTIFICATE OF ANALYSIS

品名 PRODUCT: 卡马西平CARBAMAZEPINE

代号 CODE No.: 2001-0018

批号 BATCH No.	200100A260633	质 检 SPECIFICATION	注册 Register USP
包装 PACKAGE	25.00kg/桶 drum, 52桶 drums 5.04kg/桶 drum, 1桶 drum	生产日期 MAFG DATE	2026-06
数量 QUANTITY	1305.04 kg	复验日期 RETEST DATE	2030-05

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% ✓	0.06 %
炽灼残渣 Residue on Ignition		≤0.1% ✓	<0.05 %
氯化物 Chlorides		≤0.014% ✓	<0.014 %
有机杂质 /UPLC Organic Impurities	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	≤0.1% ✓	<0.03 %
	杂质B (亚氨基苄) Iminostilbene	≤0.10% ✓	<0.03 %
	其它单个杂质 Any Other Impurity	≤0.06% ✓	0.04 %
	总杂质 Total Impurities	≤0.5% ✓	0.04 %
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_6_en-US			
结论 CONCLUSION	本品符合 注册 USP 标准规定 COMFORM WITH Register USP Standard		

制作者/日期 PREPARED BY/DATE	 2026.07.14	复核者/日期 QC MANAGER/DATE	 2026.07.14	批准人/日期 QA APPROVER /DATE	 2026.07.14
-------------------------------	---	---------------------------	--	--------------------------------	---



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, JIAOJIANG, TAIZHOU CITY, ZHEJIANG, CHINA 318000

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

WQTP-SPR-2001-11 1.0(2024-04-11)

检验报告单 CERTIFICATE OF ANALYSIS

代号CODE No.: 2001-0018

品名 PRODUCT: 卡马西平CARBAMAZEPINE

批号BATCH No.	200100A260634	标准SPECIFICATION	注册 Register USP
包装PACKAGE	25.00kg/桶 drum, 52桶 drums 4.44kg/桶 drum, 1桶 drum	生产日期MAFG DATE	2026-06
数量QUANTITY	1304.44 kg	复验日期RETEST DATE	2030-05

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 %
有机杂质 /UPLC Organic Impurities	杂质A (10,11-二氢卡马西平) 10,11-Dihydrocarbamazepine	≤0.1% ✓	<0.03 %
	杂质B (亚氨基芪) Iminostilbene	≤0.10% ✓	<0.03 %
	其它单个杂质Any Other Impurity	≤0.06% ✓	0.03 %
	总杂质Total Impurities	≤0.5% ✓	0.03 %
含量测定 (折干) /UPLC Assay (Dried Basis)		98.0~102.0% ✓	100.0 %
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_6_en-US

结论 CONCLUSION	本品符合 注册 USP 标准规定 COMFORM WITH Register USP Standard ✓		
制作者/日期 PREPARED BY/DATE	2026.07.14	复核者/日期 QC MANAGER/DATE	2026.07.14
		批准人/日期 QA APPROVER /DATE	2026.07.14