

Bagian : QC

ANALISA PERMINTAAN BARANG

Due date : 7-Sep-26

Tanggal : 10-Aug-26

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 Indeks Bias Bahan Baku Sevoflurane	Js	0	9	-9	0	9	0	0

Catatan :

- Pemenuhan parameter analisa indeks bias pada bahan baku Sevoflurane, dengan No. Batch :

1. C031241203
2. C031250401
3. C031250405
4. C031250601
5. C031250602
6. C031251210
7. C031260101
8. C031260102
9. C031260103

- Estimasi harga : Rp.300.000/Batch

- Pengujian dilakukan di PT. Saraswanti Indo Genetech

Latar belakang permintaan:

- Parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan keterbatasan alat dan penunjang. Alat refraktometer yang tersedia di lab QC Mersifarma memiliki range pembacaan di 1.30 - 1.70 sedangkan spek perhitungan Sevoflurane berada di sekitar angka 1.2 sehingga alat tidak mampu support pembacaan.

Terlampir kompendial USP terkini, spesifikasi bahan awal, CoA dan Penawaran harga.

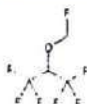
Dibuat

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Mengetahui

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Sevoflurane



$C_4H_7F_7O$ 200.05
Propane, 1,1,1,3,3,3-hexafluoro-2-(fluoromethoxy)-;
Fluoromethyl 2,2,2-trifluoro-1-(trifluoromethyl)ethyl ether
CAS RN®: 28523-86-6; UNII: 38LVP0K73A.

DEFINITION

Sevoflurane contains NLT 99.97% and NMT 100.00% of sevoflurane ($C_4H_7F_7O$).

IDENTIFICATION

• A. INFRARED ABSORPTION

Acceptance criteria: The IR absorption spectrum of Sevoflurane, obtained using a gas cell, exhibits maxima only at the same wavelengths as that of a similar preparation of USP Sevoflurane RS.

ASSAY

• PROCEDURE

Analysis: Using the results from the test for *Organic Impurities*, calculate the percentage of sevoflurane ($C_4H_7F_7O$) in the volume of Sevoflurane taken by subtracting the sum of percentages for all impurities found from 100.00%.

Acceptance criteria: 99.97%–100.00%

IMPURITIES

• LIMIT OF FLUORIDE

[NOTE—Use plastic utensils throughout this test.]

Buffer solution: Transfer 110 g of sodium chloride and 1 g of sodium citrate to a 2000-mL volumetric flask. Dissolve in 700 mL of water. Carefully add 150 g of sodium hydroxide, and shake to dissolve. Cool to room temperature, and carefully add 450 mL of glacial acetic acid while stirring. Cool, add 600 mL of isopropyl alcohol, and dilute with water to volume. [NOTE—The pH of this solution is 5.0–5.5. This solution may be used for 6 weeks when stored at room temperature.]

Solution A: Transfer 221 mg of sodium fluoride, previously dried at 150° for 4 h, to a 100-mL volumetric flask. Add about 20 mL of water, and mix to dissolve. Add 1.0 mL of 0.01 N sodium hydroxide, and dilute with water to volume. Each mL of this solution contains 1 mg of fluoride. Store in a tightly closed, plastic container. [NOTE—This solution may be used for 2 weeks when stored in a refrigerator.]

Standard stock solution 1: 0.2 µg/mL of fluoride from Solution A in water

Standard stock solution 2: 0.5 µg/mL of fluoride from Solution A in water

Standard stock solution 3: 2 µg/mL of fluoride from Solution A in water

Standard stock solution 4: 5 µg/mL of fluoride from Solution A in water

Standard solution 1: 0.10 µg/mL of fluoride from Standard stock solution 1 in Buffer solution

Standard solution 2: 0.25 µg/mL of fluoride from Standard stock solution 2 in Buffer solution

Standard solution 3: 1.0 µg/mL of fluoride from Standard stock solution 3 in Buffer solution

Standard solution 4: 2.5 µg/mL of fluoride from Standard stock solution 4 in Buffer solution

Sample solution: Pipet 50.0 mL of Sevoflurane and 50.0 mL of water into a separatory funnel, shake vigorously for 3 min, and allow the liquids to separate completely.

Transfer 25.0 mL of the aqueous top layer to a 50-mL volumetric flask, and dilute with Buffer solution to volume.

Analysis

Samples: Standard solutions 1–4 and Sample solution
Concomitantly measure the potentials, in mV, of Standard solutions 1–4 and the Sample solution with a pH meter (see pH (791)) capable of a minimum reproducibility of ±0.2 mV, and equipped with a fluoride-specific ion-indicating electrode and a glass-sleeved calomel reference electrode. When taking measurements, transfer the solution under test to a 100-mL beaker containing a polytetrafluoroethylene-coated stirring bar, and immerse the electrodes. Allow to stir on a magnetic stirrer having an insulated top until equilibrium is attained in about 2–3 min, and record the potential. Rinse the electrodes with the Buffer solution, and dry, taking care to avoid damaging the crystal of the specific-ion electrode. A satisfactory response is achieved if the difference between the potentials obtained with Standard solution 4 and Standard solution 2 is in the range between 50 and 60 mV. Plot the logarithms of the fluoride concentrations, in µg/mL, of Standard solutions 1–4 versus potentials, in mV. From the graph and the measured potential of the Sample solution, determine the concentration, C (µg/mL) of fluoride in the Sample solution. Multiply C by 2 to obtain the concentration (µg/mL) of fluoride in the portion of Sevoflurane taken.

Acceptance criteria: NMT 2 µg/mL is found.

• LIMIT OF NONVOLATILE RESIDUE

Analysis: Transfer 10.0 mL of Sevoflurane to an evaporating dish, evaporate to dryness on a steam bath, and dry the residue at 105° for 2 h.

Acceptance criteria: The weight of the residue does not exceed 1.0 mg.

• ORGANIC IMPURITIES

Internal standard solution: Use dimethoxymethane.

Ethylene dichloride identification solution: Transfer 2.0 mL of Sevoflurane to a vial, and seal with a cap and septum. Using a microsyringe, add 20 µL of ethylene dichloride through the septum of the vial, and mix thoroughly.

Sevoflurane related compounds stock solution: Transfer 20 mL of Sevoflurane to a 40-mL vial with a septum lid. Add 20 µL each of USP Sevoflurane Related Compound A RS, USP Sevoflurane Related Compound B RS, and USP Sevoflurane Related Compound C RS to the vial, and mix thoroughly.

Related compounds identification solution: Transfer 1.0 mL of Ethylene dichloride identification solution to a 10-mL volumetric flask, and dilute with Sevoflurane to volume. Transfer 2 mL of this solution and 5 mL of Sevoflurane related compounds stock solution to a 50-mL volumetric flask, dilute with Sevoflurane to volume, and mix thoroughly.

Standard solutions: Prepare in duplicate, proceeding for each as follows. Transfer 2.0 mL of ethylene dichloride to a screw-capped vial, immediately seal with a cap and septum, and place on a balance. Using a microsyringe, transfer about 20 µL of USP Sevoflurane RS to the vial by inserting the syringe needle through the septum. Record the quantity, in mg, of USP Sevoflurane RS added. Using the same method, transfer about 20 µL of the Internal standard solution to the vial, and record the quantity, in mg, of the solution added.

Control standard solution: Place a 40-mL vial with a septum lid on an analytical balance, and tare out the weight. Add 30 mL of ethylene dichloride to the vial, and seal tightly. Record the weight of the ethylene dichloride, and tare. Using a microsyringe, add 20 µL of the USP Sevoflurane RS through the septum of the vial, record the

weight, and mix thoroughly. Transfer 1.0 mL of this solution to a 100-mL volumetric flask, and dilute with ethylene dichloride to volume.

Sample solution: Transfer 20.0 mL of Sevoflurane to a vial, and insert the stopper. Using a microsyringe, add 5 µL of the *Internal standard solution* to the vial.

Chromatographic system

(See *Chromatography* (621), *System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 30-m fused-silica capillary column coated with a 3.0-µm film of liquid phase G43

Temperatures

Injection port: 200°

Detector: 225°

Column: See *Table 1*. Before use, condition the column overnight at a temperature of 250°.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	10
40	10	200	14

Carrier gas: Helium

Flow rate: 1 mL/min. [NOTE—The make-up gas flow rate is 20 mL/min.]

Injection volume: 2 µL

Injection type: Split ratio 1:20

System suitability

Samples: *Related compounds identification solution* and one of the *Standard solutions*

Suitability requirements

[NOTE—Identify the peaks using the relative retention times given in *Table 2*.]

Resolution: NLT 2.0 between sevoflurane related compound C and ethylene dichloride, *Related compounds identification solution*

Column efficiency: NLT 6000 theoretical plates for the sevoflurane peak, *Standard solution*

Relative standard deviation: NMT 3.0% from the peak area ratio of sevoflurane to the internal standard, *Standard solution*

Analysis

Samples: *Ethylene dichloride identification solution*, *Standard solutions*, *Control standard solution*, and *Sample solution*

Calculate the response factor for each of the *Standard solutions*:

$$\text{Result} = (W_i/W_s) \times R_s$$

W_i = weight of the internal standard in the *Standard solutions* (mg)

W_s = weight of USP Sevoflurane RS in the *Standard solutions* (mg)

R_s = peak area response ratio of sevoflurane to that of the internal standard from the *Standard solutions*

The response factors for the duplicate *Standard solutions* do not differ by more than 3.0% from their average.

Calculate the quantity, in µg/g, of each impurity in the portion of Sevoflurane ($C_4H_7F_7O$) taken:

$$\text{Result} = (S_1/S_2) \times (R_i/F_R) \times (1/F) \times 250$$

- S_1 = specific gravity of the internal standard, 0.859
 S_2 = specific gravity of sevoflurane, 1.525
 R_i = peak area response ratio of the impurity to that of the internal standard from the *Sample solution*
 F_R = average response factor obtained as directed above
 F = respective relative response factor for the impurities (see *Table 2*)

Acceptance criteria

[NOTE—Do not include sevoflurane, the internal standard, or any peak identified as solvent carryover (ethylene dichloride). Also, disregard any peak with an area less than 30% of the average area of the principal peak from the *Control standard solution*.]

Individual impurities: NMT 25 µg/g of sevoflurane related compound A and NMT 100 µg/g of any other single impurity

Total impurities: NMT 300 µg/g

Table 2

Name	Relative Retention Time	Relative Response Factor
Sevoflurane related compound A	0.78	1.0
Sevoflurane related compound B	0.83	1.0
Sevoflurane	1.0	—
Internal standard (dime-thoxymethane)	1.35	—
Ethylene dichloride	2.28	—
Sevoflurane related compound C	2.31	0.46
Unknown impurities	—	1

SPECIFIC TESTS

• **REFRACTIVE INDEX (831):** 1.2745–1.2760 at 20°

• **ACIDITY OR ALKALINITY:** Transfer 20.0 mL of Sevoflurane and 20.0 mL of carbon dioxide-free water to a separatory funnel, shake for 3 min, and allow the layers to separate.

Acceptance criteria: The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization, bromocresol purple TS being used as the indicator.

• **WATER DETERMINATION, Method I (921):** NMT 0.1%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at controlled room temperature. Replace the cap securely after each use.

• **USP REFERENCE STANDARDS (11)**

USP Sevoflurane RS

USP Sevoflurane Related Compound A RS

1,1,1,3,3-Pentafluoroisopropenyl fluoromethyl ether.
 $C_4H_2F_6O$ 180.05

USP Sevoflurane Related Compound B RS

1,1,1,3,3,3-Hexafluoro-2-methoxy-propane.
 $C_4H_4F_6O$ 182.06

USP Sevoflurane Related Compound C RS

1,1,1,3,3,3-Hexafluoro-2-propanol.
 $C_3H_2F_6O$ 168.04

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DIVISI MANUFACTURING
SUKABUMI-INDONESIA

SPESIFIKASI BAHAN AWAL SEVOFLURANE

Halaman 1 dari 1

Nomor Dokumen :
2RD20/SPBAA/156.01

Tanggal berlaku :
31 Oktober 2019

**DEPARTEMEN
RESEARCH AND DEVELOPMENT**

**SEKSI
ANALYTICAL DEVELOPMENT**

Disusun Oleh :

Diperiksa Oleh :

Disetujui Oleh :

Ayu Halida S. Farm. Apt.

Juliana M. S. Farm. Apt.

A. Muhyadi S. Si.

Selvi S. Farm. Apt.

Parmin S. Si. Apt.

Pengganti No :
2RD20/SPBAA/156.00

Tanggal :
02 Juli 2018

R&D Staff

R&D Supervisor

R&D Manager

QA Manager

Plant Manager

Tanggal : 10/10

Tanggal : 11/10

Tanggal : 14/10

Tanggal : 15/10

Tanggal : 16/10

PUSTAKA

1. United State Pharmacopeia 40, NF 35, 2017, hal. 2501; 6152 - 6154
2. Metode Internal

PEMERIAN ⁽¹⁾

Jernih, tidak berwarna, mudah menguap, larutan tidak mudah terbakar.

KELARUTAN ⁽¹⁾Sukar larut dalam air. Dapat dicampur dengan *alcohol*, dengan *chloroform*, dan dalam *ether*.**IDENTIFIKASI ⁽¹⁾**

Sampel memberikan respon yang sama seperti standar.

BATAS FLUORIDE ⁽¹⁾ $\leq 2 \mu\text{g/mL}$.**SISA PENGUAPAN ⁽¹⁾** $\leq 1 \text{ mg}$.**CEMARAN ORGANIK ⁽¹⁾**

Senyawa sejenis A $\leq 25 \text{ ppm}$
Pengotor lain $\leq 100 \text{ ppm}$
Total pengotor $\leq 300 \text{ ppm}$

**DUPLIKAT
TERKENDALI**

**ASIDITAS ATAU
ALKALINITAS ⁽¹⁾** $\leq 0.10 \text{ mL NaOH } 0.010 \text{ N}$ atau $\leq 0.60 \text{ mL HCl } 0.010 \text{ N}$.**INDEKS BIAS ⁽¹⁾**

1.2745 - 1.2760 Pada 20°

AIR ⁽¹⁾ $\leq 0.1\%$ **PENETAPAN KADAR ⁽¹⁾**

99.97 % - 100.00%

**WADAH DAN
PENYIMPANAN ⁽¹⁾**

Dalam wadah tertutup rapat dan terlindung dari cahaya, tempatkan pada suhu ruang terkendali. Tutup kembali setelah digunakan.

SEJARAH PERUBAHAN :

1. 2RD20/SPBAA/156.00 : - Pertamakali diberlakukan di Departemen R&D.
2. 2RD20/SPBAA/156.01 : - Menggantikan no. 2RD20/SPBAA/156.00
- Update pustaka USP 40. Metode Internal.

Asli : Pusat Dokumentasi Departemen QA

Salinar : 1. Arsip Departemen R&D

2. Laboratorium R&D

3. Departemen QC

HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031241203
Batch No.	C031241203	Batch Quantity	3625.0kg
Mfg. Date	2024.11.22	Exp. Date	2027.10
Specification	USP 47	Report Date	2024.12.21

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.06mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.02µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	2µg/g 12µg/g 31µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.997%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 孙小一

Reviewed by: 刘雅

QC Manager: 李谦

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA

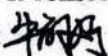
HEBEI YIPIN PHARMACEUTICAL CO., LTD.

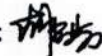
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031250401
Batch No.	C031250401	Batch Quantity	3600.0kg
Mfg. Date	2025.01.24	Exp. Date	2027.12
Specification	USP 47	Report Date	2025.08.04

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.01µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.2mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	3µg/g 12µg/g 27µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.997%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 

Reviewed by: 

QC Manager: 

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA



29/08

HEBEI YIPIN PHARMACEUTICAL CO., LTD.

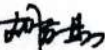
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031250405
Batch No.	C031250405	Batch Quantity	3600.0kg
Mfg. Date	2024.10.06	Exp. Date	2027.09
Specification	USP 47	Report Date	2025.08.04

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2753	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.05mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.04µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	Not detected 33µg/g 35µg/g	Conforms
Water	NMT 0.1%	0.07%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.996%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 

Reviewed by: 

QC Manager: 

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA



29/08

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CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031250601
Batch No.	C031250601	Batch Quantity	3600.0kg
Mfg. Date	2025.04.22	Exp. Date	2028.03
Specification	USP 47	Report Date	2025.07.16

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2753	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.05mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.04µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.2mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	5µg/g 23µg/g 37µg/g	Conforms
Water	NMT 0.1%	0.04%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.996%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 牛初阳

Reviewed by: 胡志书

QC Manager: 唐燕

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA



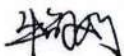
HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031250602
Batch No.	C031250602	Batch Quantity	3600.0kg
Mfg. Date	2025.04.29	Exp. Date	2028.03
Specification	USP 47	Report Date	2025.07.16

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.05mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.04µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	Not detected 25µg/g 52µg/g	Conforms
Water	NMT 0.1%	0.04%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 

Reviewed by: 

QC Manager: 

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA



HEBEI YIPIN PHARMACEUTICAL CO., LTD.

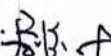
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031251210
Batch No.	C031251210	Batch Quantity	4200.0kg
Mfg. Date	2025.11.16	Exp. Date	2030.10
Specification	USP 47	Report Date	2026.04.10

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754 at 20°	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.1µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.2mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	3µg/g 26µg/g 61µg/g	Conforms
Water	NMT 0.1%	0.02%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 

Reviewed by: 

QC Manager: 

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA

HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031260101
Batch No.	C031260101	Batch Quantity	4200.0kg
Mfg. Date	2025.11.23	Exp. Date	2030.10
Specification	USP 47	Report Date	2026.04.17

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754 at 20°	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.1µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	13µg/g 32µg/g 65µg/g	Conforms
Water	NMT 0.1%	0.01%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 郝强

Reviewed by: 牛明

QC Manager: 李源

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA

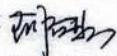
HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031260102
Batch No.	C031260102	Batch Quantity	4200.0kg
Mfg. Date	2025.11.29	Exp. Date	2030.10
Specification	USP 47	Report Date	2026.04.17

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2755 at 20°	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.1µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.1mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	12µg/g 43µg/g 88µg/g	Conforms
Water	NMT 0.1%	0.01%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 

Reviewed by: 

QC Manager: 

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA

HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031260103
Batch No.	C031260103	Batch Quantity	4200.0kg
Mfg. Date	2025.12.04	Exp: Date	2030.11
Specification	USP 47	Report Date	2026.04.17

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754 at 20°	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.1µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.1mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	8µg/g 42µg/g 104µg/g	Conforms
Water	NMT 0.1%	0.02%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 刘阳

Reviewed by: 李海

QC Manager: 李海

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI CHINA

LIST PARAMETER BAHAN BAKU BELUM BISA DIKERJAKAN OLEH QC

No.	Parameter	Nama Bahan	Kendala di QC	Keterangan (Bisa/Tidak oleh R&D)
46	Pirogen	Paracetamol 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
47	Indeks Bias	Sevoflurane	Alat refraktometer yang tersedia di lab QC Mersifarma memiliki range pembacaan di 1.30 - 1.70 sedangkan spek perhitungan sevoflurane 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
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 terdapat pengembangan metode dan validasi metode oleh RnD	Belum terdapat kolom G27 5 um 0.53 mm x 5 m, belum terdapat 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

Munawar 15/26
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Kepada Yth
Robertus Luki Praptono
PT. Mersifarma Tirmaku Mercusana
Robertus_Praptono@mersifarma.com
+62 8157962741 / +62 266321877

Nomor Penawaran
Tanggal

: SIG.MARK.PN.IX.2024.032844
: 06 September 2024

Dengan Hormat.

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

1. Isoflurane

NO	JENIS	PARAMETER	PENGUJIAN	HARGA (IDR)
1	Non Paket	Klorida (Cl)	Normal	165,000
Subtotal				165,000

2. Isoflurane

NO	JENIS	PARAMETER	PENGUJIAN	HARGA (IDR)
1	Non Paket	Fluorida	Normal	385,000
Subtotal				385,000

3. Sevoflurane

NO	JENIS	PARAMETER	PENGUJIAN	HARGA (IDR)
1	Non Paket	Fluorida	Normal	385,000
Subtotal				385,000

4. Isoflurane

NO	JENIS	PARAMETER	PENGUJIAN	HARGA (IDR)
1	Non Paket	Indeks Bias	Normal	300,000
Subtotal				300,000

5. Sevoflurane

NO	JENIS	PARAMETER	PENGUJIAN	HARGA (IDR)
1	Non Paket	Indeks Bias	Normal	300,000
Subtotal				300,000

BIAYA PENGUJIAN (IDR)	
Subtotal	1,535,000
PPN (11%)	168,850
Total	1,703,850

Catatan

- Dilampirkan surat penawaran ini saat pengiriman sampel pengujian

Towards
a safer world

PT SARASWANTI INDO GENETECH
Graha SIG Jl. Rasamala No. 20 Taman Yasmin
Bogor 16113 INDONESIA
Phone +62 251 7532 348 49 (Hunting), 0821 1151 6516
Fax +62 251 7540 927
www.siglaboratory.com

