

Bagian : QC

Due date : 30-Apr-26

Tanggal : 30-Mar-26

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 Indeks Bias Sevoflurane 250 ml	Js	0	3	-3	0	3	0	0
1	IMO10028	Jasa analisa Indeks Bias Isoflurane 250 ml	Js	0	4	-4	0	4	0	0

Catatan :

- Pemenuhan parameter analisa indeks bias pada produk Isoflurane 250 ml dan Sevoflurane 250 ml, dengan No. Batch:

1. Sevoflurane 250 ml batch : K60014
2. Sevoflurane 250 ml batch : K60015
3. Sevoflurane 250 ml batch : K60016
4. Isoflurane 250 ml batch : K60017
5. Isoflurane 250 ml batch : K60018
6. Isoflurane 250 ml batch : K60019
7. Isoflurane 250 ml batch : K60020

- Estimasi harga pengujian : 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 Isoflurane dan sevoflurane berada di sekitar angka 1.2 sehingga alat tidak mampu support pembacaan

- Sebagai pemenuhan regulasi dan perilsan produk Isoflurane 250 ml dan Sevoflurane 250 ml

- Terlampir Spesifikasi produk, USP terkini dan Penawaran harga

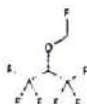
Dibuat -

30/26
03

Mengetahui

30/02

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

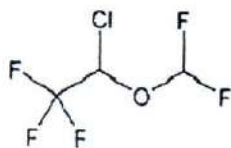
USP Sevoflurane Related Compound B RS

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

Handwritten signature and date: 1/5/24

Isoflurane

184.49

Ethane, 2-chloro-2-(difluoromethoxy)-1,1,1-trifluoro-;
1-Chloro-2,2,2-trifluoroethyl difluoromethyl ether
CAS RN®: 26675-46-7; UNII: CYS9AKD70P.

DEFINITION

Isoflurane contains NLT 99.9% and NMT 100.0% of isoflurane ($\text{C}_3\text{H}_2\text{ClF}_5\text{O}$).

IDENTIFICATION

- A.** The IR absorption spectrum of Isoflurane, obtained using a gas cell, exhibits maxima only at the same wavelengths as those of a similar preparation of USP Isoflurane RS.

ASSAY**PROCEDURE**

Analysis: Using the results from the test for *Organic Impurities*, calculate the percentage of isoflurane ($\text{C}_3\text{H}_2\text{ClF}_5\text{O}$) in the sample of Isoflurane taken by subtracting the sum of percentages for the impurities found from 100.0%.

Acceptance criteria: 99.9%–100.0%

IMPURITIES**CHLORIDE**

Sample solution: Pipet 10 mL of Isoflurane into a suitable vessel containing 60 mL of isopropyl alcohol and 4 drops of dilute nitric acid (1:1), and stir to dissolve.

Analysis: Titrate potentiometrically with 0.002 N silver nitrate in isopropyl alcohol VS.

Acceptance criteria: NMT 2.11 mL is required (NMT 10 ppm)

LIMIT OF FLUORIDE

Use plasticware throughout this test.

Buffer: Dissolve 110 g of sodium chloride and 1 g of sodium citrate in 700 mL of water in a 2-L volumetric flask. Cautiously add 150 g of sodium hydroxide, and dissolve with shaking. Cool to room temperature, and, while stirring, cautiously add 450 mL of glacial acetic acid to the cooled solution. Cool, add 600 mL of isopropyl alcohol, dilute with water to volume, and mix. The pH of this solution is between 5.0 and 5.5. [NOTE—This solution may be used for 6 weeks if stored at room temperature.]

Solution A: Transfer 55 mg of USP Sodium Fluoride RS to a 25-mL volumetric flask. Add 5 mL of water, and mix to dissolve. Add 1.0 mL of 0.0025 N sodium hydroxide, dilute with water to volume, and mix. Each mL of this solution contains 1 mg of fluoride ion. Store in a tightly closed plastic container. [NOTE—This solution may be used for 2 weeks if stored in a refrigerator.]

Standard stock solution 1: 2.0 µg/mL of fluoride in water from Solution A

Standard stock solution 2: 6.0 µg/mL of fluoride in water from Solution A

Standard stock solution 3: 10.0 µg/mL of fluoride in water from Solution A

Standard stock solution 4: 20.0 µg/mL of fluoride in water from Solution A

Standard solution 1: 1.0 µg/mL of fluoride in Buffer from Standard stock solution 1

Standard solution 2: 3.0 µg/mL of fluoride in Buffer from Standard stock solution 2

Standard solution 3: 5.0 µg/mL of fluoride in Buffer from Standard stock solution 3

Standard solution 4: 10.0 µg/mL of fluoride in Buffer from Standard stock solution 4

Sample solution: Shake 50.0 mL of Isoflurane with 50.0 mL of water for 5 min, and allow the liquids to separate completely. Transfer 25.0 mL of the water layer to a 50-mL volumetric flask, dilute with Buffer to volume, and mix.

Analysis

Samples: Standard solutions 1–4 and Sample solution (See pH (791).)

Concomitantly measure the potentials in mV, of Standard solutions 1–4 and the Sample solution with a pH meter capable of a minimum reproducibility of ± 0.2 mV and equipped with a fluoride ion electrode and a glass-sleeved calomel reference electrode or a double-junction fluoride ion-selective combination electrode. When taking measurements, immerse the electrodes in the solution under test, which has been transferred to a 150-mL beaker containing a polytetrafluoroethylene-coated stirring bar. Allow to stir on a magnetic stirrer with an insulated top until equilibrium is attained (1–2 min), and record the potential. Rinse and dry the electrodes between measurements, taking care to avoid damaging the crystal of the fluoride ion electrode.

A satisfactory response is achieved if the difference in potential between the potentials obtained with Standard solution 1 and Standard solution 4, having fluoride concentrations of 1.0 and 10.0 µg/mL, respectively, is in the range of 50–60 mV. Plot the logarithm of the fluoride ion concentrations, in µg/mL, of Standard solutions 1–4 versus potential, in mV. From the measured potential of the Sample solution and the standard response line, determine the concentration, in µg/mL, of fluoride in the Sample solution.

Acceptance criteria: NMT 5 µg/mL of fluoride in the Sample solution [NMT 0.001% (w/v) fluoride in Isoflurane]

NONVOLATILE RESIDUE

Analysis: Transfer 10.0 mL of Isoflurane to a suitable weighed evaporating dish, evaporate with the aid of a current of air or stream of nitrogen to dryness, and dry the residue at 50° for 2 h.

Acceptance criteria: The weight of the residue does not exceed 2.0 mg.

Change to read:**ORGANIC IMPURITIES**

Standard stock solution: To a suitable tared vial, fitted with a septum, add 20 mL (29.8 g) of Isoflurane. Seal and reweigh the vial to determine the weight of the Isoflurane added. To this vial sequentially add 20 µL (30 mg) of USP Isoflurane Related Compound A RS, 21 µL (30 mg) of USP Isoflurane Related Compound B RS, and 38 µL (30 mg) of USP Acetone RS. Record the weight after the addition of each impurity and determine the total weight. Calculate the percentage of each impurity in the Standard stock solution:

$$\text{Result} = (W_i/W_T) \times P_i$$

W_i = weight of each impurity added (g)
 W_T = total weight of the Standard stock solution (g)
 P_i = purity of each impurity added (%)

Standard solution: To a suitable tared vial, fitted with a septum, add 10 mL (15 g) of Isoflurane. Seal and reweigh the vial to determine the weight of the Isoflurane added.

To this vial add 300 μ L of the *Standard stock solution*, and record the weight to determine the weight of the *Standard stock solution* added and the final weight of the *Standard solution*.

Calculate the spiked concentration (C_s) of each impurity in the *Standard solution*:

$$\text{Result} = (W_i/W_T) \times C_i$$

W_i = weight of the *Standard stock solution* added (g)

W_T = total weight of the *Standard solution* (g)

C_i = concentration of each impurity in the *Standard stock solution* (%)

System suitability solution: To a suitable vial, fitted with a septum, add 10 mL (15 g) of Isoflurane. Seal the vial. To this vial add 100 μ L of the *Standard stock solution*.

Sample solution: Isoflurane

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm $\times$ 60-m; fused-silica capillary coated with a 1.0- μ m film of G16

Carrier gas: Helium

Flow rate: 1.7 mL/min (constant flow mode)

Temperatures

Injection port: 175°

Detector: 200°

Column: See Table 1.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	—	40	8
40	10	170	4

Injection volume: 2 μ L

Injection type: Split; split ratio, 23:1

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Tailing factor: NMT 1.5 for acetone, *Standard solution*

Relative standard deviation: NMT 5% each for isoflurane related compound A, isoflurane related compound B, and acetone, *Standard solution*

Signal-to-noise ratio: NLT 15 for isoflurane related compound B, *System suitability solution*

Analysis: Injections of Isoflurane used to prepare the *Standard solution* must be made to estimate the amount of known impurities that may be present in the solvent. The final concentration of each impurity is equal to the concentration of the impurity added plus the concentration inherent in the matrix.

Samples: *Standard solution* and *Sample solution*

Calculate the final concentration (C_f) of each impurity in the *Standard solution*:

$$\text{Result} = [r_U/(r_s - r_U) \times C_s] + C_s$$

r_U = peak response of each impurity from the isoflurane used as the solvent

r_s = peak response of each impurity from the *Standard solution*

C_s = spiked concentration of each impurity in the *Standard solution* (%)

Calculate the percentage of isoflurane related compound A, isoflurane related compound B, and acetone observed in the *Sample solution*:

$$\text{Result} = (r_U/r_s) \times C_f$$

r_U = peak response of each impurity from the *Sample solution*

r_s = peak response of each impurity from the *Standard solution*

C_f = final concentration of each impurity in the *Standard solution* (%)

Calculate the percentage of all other impurities:

$$\text{Result} = (r_U/r_s) \times {}^A C_{FA} (\text{ERR 1-May-2023}) \times (1/F)$$

r_U = peak response of the impurity from the *Sample solution*

r_s = peak response of isoflurane related compound B from the *Standard solution*

${}^A C_{FA} (\text{ERR 1-May-2023})$ = final concentration of USP Isoflurane Related Compound B RS in the *Standard solution* (%)

F = relative response factor relative to isoflurane related compound B (see Table 2)

Acceptance criteria: See Table 2.

Table 2

Name	Relative Retention Time ^a	Relative Response Factor ^b	Acceptance Criteria, NMT (%)
Dichloroisoflurane ^c	0.41	0.28	0.003
Isoflurane isomer ^d	0.43	0.87	0.003
Isoflurane related compound A	0.46	—	0.01
Isoflurane related compound B	0.56	1.00	0.007
Chloroisoflurane ^e	0.59	0.35	0.003
Acetone	0.79	—	0.008
Isoflurane	1.00	—	—
Any individual unspecified impurity	—	1.00	0.003
Total impurities	—	—	0.1

^a Relative to isoflurane.

^b Relative to isoflurane related compound B.

^c 1,1-Dichloro-1-(chlorodifluoromethoxy)-2,2,2-trifluoroethane.

^d 2-(Chlorodifluoromethoxy)-1,1,1-trifluoroethane.

^e 1,1-Dichloro-1-(difluoromethoxy)-2,2,2-trifluoroethane.

SPECIFIC TESTS

• **REFRACTIVE INDEX** (831): 1.2990–1.3005 at 20°

• **WATER DETERMINATION** (921), *Method I*: NMT 0.10%

• **ACIDITY OR ALKALINITY**

Sample: Transfer 5 mL of Isoflurane and 2 mL of carbon dioxide-free water to a 10-mL glass-stoppered graduated cylinder, shake for 3 min, and allow the layers to separate.

Analysis: Test the aqueous layer (upper) with both red litmus paper and blue litmus paper.

Acceptance criteria: The aqueous layer is neutral to litmus paper. The aqueous phase should not turn the red litmus paper blue, nor should it turn the blue litmus paper red.

 mersi PT. MERSIFARMA TM. DIVISI MANUFACTURING SUKABUMI-INDONESIA	SPESIFIKASI PRODUK SEVOFLURANE 250 mL INHALASI			Halaman 1 dari 1 No Dokumen : 2RD10/SPSPG/322.02 Tanggal berlakunya : 18 Agustus 2020																												
Disusun oleh :	DEPARTEMEN RESEARCH AND DEVELOPMENT	SEKSI FORMULASI		Pengganti N : 2RD10/SPSPG/322.01 Tanggal : 13 April 2020																												
 R&D Staff Formulasi Tanggal : 27/10/20	 R&D Asst/ Mgr Formulasi Tanggal : 28/10/20	 QA Asst/ Mgr Tanggal : 29/10/20	 Plant Mgr Tanggal : 29/10/20																													
Nama Sediaan	Sevoflurane 250 mL																															
Bentuk Sediaan	Cairan																															
Bahan Aktif Tiap Satuan Dosis	Sevoflurane 250 mL																															
Pustaka	USP 40, Vol. 3, 2017, hal. 6152 - 6154. Spesifikasi Internal																															
Pemerian	Cairan jernih dan tidak berwarna, mudah menguap, tidak mudah terbakar																															
Karakteristik Fisika/ Kimia	<table border="0"> <tr> <td>1. Identifikasi</td> <td>Sampel memberikan respon yang sama seperti standar</td> </tr> <tr> <td>2. Kadar</td> <td>: 99.97 % - 100.00%</td> </tr> <tr> <td>3. Volume</td> <td>: 250.00 - 258.00 mL</td> </tr> <tr> <td>4. Batas Fluoride*</td> <td>: Maks. 2 µg/mL</td> </tr> <tr> <td>5. Sisa penguapan</td> <td>: Maks. 1.0 mg</td> </tr> <tr> <td>6. Cemaran Organik</td> <td>: Maks. 300 ppm</td> </tr> <tr> <td></td> <td>Senyawa sejenis A : maks. 25 ppm</td> </tr> <tr> <td></td> <td>Pengotor lain : maks. 100 ppm</td> </tr> <tr> <td></td> <td>Total pengotor : maks. 300 ppm</td> </tr> <tr> <td>7. Asiditas atau Alkalinitas</td> <td>: maks. 0.10 mL NaOH 0.010 N atau maks. 0.60 mL HCl 0.010 N</td> </tr> <tr> <td>8. Indeks Bias*</td> <td>: 1.2745 - 1.2760 Dalam 20°C</td> </tr> <tr> <td>9. Kadar Air</td> <td>: Maks. 0.10 %</td> </tr> <tr> <td>10. Partikel</td> <td>: Partikel dan serat < 10</td> </tr> <tr> <td>11. Klorida</td> <td>: maks. 2.11 mL AgNO3 0.0020 N</td> </tr> </table>				1. Identifikasi	Sampel memberikan respon yang sama seperti standar	2. Kadar	: 99.97 % - 100.00%	3. Volume	: 250.00 - 258.00 mL	4. Batas Fluoride*	: Maks. 2 µg/mL	5. Sisa penguapan	: Maks. 1.0 mg	6. Cemaran Organik	: Maks. 300 ppm		Senyawa sejenis A : maks. 25 ppm		Pengotor lain : maks. 100 ppm		Total pengotor : maks. 300 ppm	7. Asiditas atau Alkalinitas	: maks. 0.10 mL NaOH 0.010 N atau maks. 0.60 mL HCl 0.010 N	8. Indeks Bias*	: 1.2745 - 1.2760 Dalam 20°C	9. Kadar Air	: Maks. 0.10 %	10. Partikel	: Partikel dan serat < 10	11. Klorida	: maks. 2.11 mL AgNO3 0.0020 N
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Penyimpanan	Simpan di bawah suhu 30°C, terlindung dari cahaya																															

 PT. MERSIFARMA TM. DIVISI MANUFACTURING SUKABUMI-INDONESIA	SPESIFIKASI PRODUK ISOFLURANE 250 mL INHALASI			Halaman 1 dari 1 No. Dokumen 2RD10/SPSPG/32 03 Tanggal berlaku : 11 September 2020																																								
Disusun oleh :	Diperiksa oleh :	Disetujui oleh :	Disetujui oleh :	Pengganti No. : 2RD10/SPSPG/32 02																																								
 R&D Staff Formulasi Tanggal : 24/8/20	 R&D Asst/Mgr Formulasi Tanggal : 24/8/20	 QA Asst / Mgr Tanggal : 25/8/20	 Plant Mgr Tanggal : 26/8/20	Tanggal : 18 Agustus 2020																																								
Nama Sediaan	Isoflurane 250 mL																																											
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Bahan Aktif Tiap Satuan Dosis	Isoflurane 250 mL																																											
Pustaka	USP 40 Tahun 2017 Vol. II Hal. 4688 - 4690, Spesifikasi Internal																																											
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