

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	IMO11462	Kolom XBridge C18	Un	0	1	-1	0	1	0	0

Catatan :

Kolom Xbridge C18 (5µm) 150mm x 4.6mm Part. No: 186003116

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewati fase gerak melalui kolom.
- Kolom tersebut digunakan untuk penetapan kadar dan cemaran organik pada bahan baku metil paraben dan propil paraben.
- Pemesanan terakhir pada bulan Desember 2025 (PW027893)
- Estimasi harga: Rp.26.405.568

Latar Belakang Permintaan

- Sehubung dengan update metode pemeriksaan bahan baku metil paraben dan propil paraben sesuai dengan USP 47 maka diperlukan pengadaan kolom tersebut.
- Terlampir USP 47, metode analisa, rencana kebutuhan dan penawaran harga.

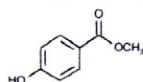
Pemohon


.....

Mengetahui


.....

Methylparaben



$C_8H_8O_3$ 152.15
Benzoic acid, 4-hydroxy-, methyl ester;
Methyl *p*-hydroxybenzoate CAS RN®: 99-76-3.

DEFINITION

Methylparaben contains NLT 98.0% and NMT 102.0% of $C_8H_8O_3$.

IDENTIFICATION

Change to read:

- **A. Δ SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197M Δ** (CN 1-May-2020)
- **B. MELTING RANGE OR TEMPERATURE** (741): 125°–128°

ASSAY

PROCEDURE

Mobile phase, Sample solution, Standard solution B, and Chromatographic system: Proceed as described in the procedure for *Related Substances*.

System suitability

Sample: *Standard solution B*

Suitability requirements

Relative standard deviation: NMT 0.85% for 6 injections

Analysis

Samples: *Sample solution* and *Standard solution B*

Calculate the percentage of Methylparaben in the *Sample solution*:

$$\text{Result} = P \times (r_U \times C_S) / (r_S \times C_U)$$

- P = labeled purity of USP Methylparaben RS expressed as a percentage
 r_U = peak area of methylparaben from the *Sample solution*
 C_S = concentration of methylparaben in *Standard solution B*
 r_S = peak area of methylparaben from *Standard solution B*
 C_U = concentration of Methylparaben in the *Sample solution*

Acceptance criteria: 98.0%–102.0%

IMPURITIES

INORGANIC IMPURITIES

- **Residue on Ignition** (281): NMT 0.1%, determined on 1.0 g

ORGANIC IMPURITIES

Procedure: *Related Substances*

Mobile phase: Methanol and a 6.8 g/L solution of potassium dihydrogen phosphate (65:35 v/v)

Sample solution: Dissolve 50.0 mg of Methylparaben in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Standard solution A: 5.0 μ g/mL each of *p*-hydroxy benzoic acid and USP Methylparaben RS in *Mobile phase*

Standard solution B: Dissolve 50.0 mg of USP Methylparaben RS in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Standard solution C: Dilute 1.0 mL of the *Sample solution* with *Mobile phase* to 20.0 mL. Dilute 1.0 mL of this solution with *Mobile phase* to 10.0 mL.

Chromatographic system

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

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing L1

Flow rate: 1.3 mL/min

Injection size: 10 μ L

Run time: About 5 times the retention time of methylparaben

System suitability

Sample: *Standard solution A*

[NOTE—The retention time of methylparaben is about 2.3 min; the relative retention time for *p*-hydroxy benzoic acid is about 0.6.]

Suitability requirements

Resolution: NLT 2.0 between the *p*-hydroxybenzoic acid and methylparaben peaks

Analysis

Samples: *Sample solution* and *Standard solution C*

[NOTE—Disregard any limit that is 0.2 times the area of the principal peak in the chromatogram obtained with *Standard solution C* (0.1%).]

Acceptance criteria

***p*-Hydroxybenzoic acid:** The peak area in the *Sample solution*, multiplied by 1.4 to correct for the calculation of content, is NMT the area of the principal peak in *Standard solution C* (0.5%).

Unspecified impurities: The peak area of each impurity in the *Sample solution* is NMT the area of the principal peak in *Standard solution C* (0.5%).

Total impurities: The total peak area for all impurities in the *Sample solution* is NMT twice the area of the principal peak in *Standard solution C* (1.0%).

SPECIFIC TESTS

COLOR OF SOLUTION

Sample solution: 100 mg/mL in alcohol

Comparison solution: Mix 2.4 mL of ferric chloride CS, 1.0 mL of cobaltous chloride CS, and 0.4 mL of cupric sulfate CS with 0.3 N hydrochloric acid to make 10 mL. Dilute 5 mL of this solution with 0.3 N hydrochloric acid to make 100 mL. [NOTE—Prepare and use this solution immediately.]

Analysis

Samples: Alcohol, *Sample solution*, and *Comparison solution*

Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* (631)).

Acceptance criteria: The *Sample solution* is clear and not more intensely colored than alcohol or the *Comparison solution*.

ACIDITY

Sample solution: To 2 mL of the *Sample solution* prepared in the test for *Color of Solution*, add 3 mL of alcohol, 5 mL of carbon dioxide-free water, and 0.1 mL of bromocresol green TS.

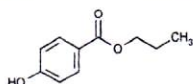
Analysis: Titrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 0.1 mL is required to produce a blue color.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** (11)
USP Methylparaben RS

Propylparaben



$C_{10}H_{12}O_3$ 180.20
Benzoic acid, 4-hydroxy-, propyl ester;
Propyl *p*-hydroxybenzoate CAS RN®: 94-13-3.

DEFINITION

Propylparaben contains NLT 98.0% and NMT 102.0% of $C_{10}H_{12}O_3$.

IDENTIFICATION

Change to read:

- **A. ^ΔSPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197M_Δ** (CN 1-May-2020)
- **B. MELTING RANGE OR TEMPERATURE** (741): 96°–99°

ASSAY

PROCEDURE

Mobile phase, Sample solution, Standard solution B, and Chromatographic system: Proceed as described in the procedure for *Related Substances*.

System suitability

Sample: Standard solution B

Suitability requirements

Relative standard deviation: NMT 0.85% for 6 injections

Analysis

Samples: Sample solution and Standard solution B
Calculate the percentage of Propylparaben in the Sample solution:

$$\text{Result} = P \times (r_U \times C_S) / (r_S \times C_U)$$

- P = labeled purity of USP Propylparaben RS expressed as a percentage
 r_U = peak area of propylparaben from the Sample solution
 C_S = concentration of propylparaben in Standard solution B
 r_S = peak area of propylparaben from Standard solution B
 C_U = concentration of Propylparaben in the Sample solution

Acceptance criteria: 98.0%–102.0%

IMPURITIES

INORGANIC IMPURITIES

- **Residue on Ignition** (281): NMT 0.1%, determined on 1.0 g

ORGANIC IMPURITIES

Procedure: Related Substances

Mobile phase: Methanol and a 6.8 g/L solution of potassium dihydrogen phosphate (65:35 v/v)

Sample solution: Dissolve 50.0 mg of Propylparaben in 2.5 mL of methanol, and dilute with Mobile phase to 50.0 mL. Dilute 10.0 mL of this solution with Mobile phase to 100.0 mL.

Standard solution A: 5.0 µg/mL each of *p*-hydroxy benzoic acid, USP Ethylparaben RS, and USP Propylparaben RS in Mobile phase

Standard solution B: Dissolve 50.0 mg of USP Propylparaben RS in 2.5 mL of methanol, and dilute with Mobile phase to

50.0 mL. Dilute 10.0 mL of this solution with Mobile phase to 100.0 mL.

Standard solution C: Dilute 1.0 mL of the Sample solution with Mobile phase to 20.0 mL. Dilute 1.0 mL of this solution with Mobile phase to 10.0 mL.

Chromatographic system

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

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.3 mL/min

Injection size: 10 µL

Run time: About 2.5 times the retention time of propylparaben

System suitability

Sample: Standard solution A

[NOTE—The retention time of propylparaben is about 4.5 min; the relative retention times for *p*-hydroxy benzoic acid and ethylparaben are about 0.3 and 0.7, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the ethylparaben and propylparaben peaks

Analysis

Samples: Sample solution and Standard solution C

[NOTE—Disregard any limit that is 0.2 times the area of the principal peak in the chromatogram obtained with Standard solution C (0.1%).]

Acceptance criteria

***p*-Hydroxybenzoic acid:** The peak area in the Sample solution, multiplied by 1.4 to correct for the calculation of content, is NMT the area of the principal peak in Standard solution C (0.5%).

Unspecified impurities: The peak area of each impurity in the Sample solution is NMT the area of the principal peak in Standard solution C (0.5%).

Total impurities: The total peak area for all impurities in the Sample solution is NMT twice the area of the principal peak in Standard solution C (1.0%).

SPECIFIC TESTS

COLOR OF SOLUTION

Sample solution: 100 mg/mL in alcohol

Comparison solution: Mix 2.4 mL of ferric chloride CS, 1.0 mL of cobaltous chloride CS, and 0.4 mL of cupric sulfate CS with 0.3 N hydrochloric acid to make 10 mL. Dilute 5 mL of this solution with 0.3 N hydrochloric acid to make 100 mL. [NOTE—Prepare and use this solution immediately.]

Analysis

Samples: Alcohol, Sample solution, and Comparison solution

Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* (631)).

Acceptance criteria: The Sample solution is clear and not more intensely colored than alcohol or the Comparison solution.

ACIDITY

Sample solution: To 2 mL of Sample solution prepared in the test for Color of Solution, add 3 mL of alcohol, 5 mL of carbon dioxide-free water, and 0.1 mL of bromocresol green TS.

Analysis: Titrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 0.1 mL is required to produce a blue color.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.



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PROTOKOL TRANSFER METODE ANALISA
PENETAPAN KADAR DAN CEMARAN ORGANIK
BAHAN BAKU METILPARABEN
TRANSFER PROTOCOL FOR ANALYSIS METHOD
FOR DETERMINING CONTENT AND ORGANIC
IMPURITY OF METHYLPARABEN RAW
MATERIALS

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Documen Number :
Tanggal Dokumen Disetujui :
Document Approved Date :
Menggantikan No. :
Replaces No. :

4.2.2. Metode : High Performance Liquid Chromatography
Method High Performance Liquid Chromatography

4.2.3. Kondisi pengerjaan HPLC
HPLC Operating Conditions

- 4.2.3.1. Kolom : Kolom XBridge C18 150 mm x 4.6 mm, 5 μ m (L1).
Column : C18 150 mm x 4.6 mm, 5 μ m XBridge column (L1).
- 4.2.3.2. Laju alir : 1.3 mL/menit.
Flow rate : 1.3 mL/minutes.
- 4.2.3.3. Panjang gelombang detektor : 272 nm.
Detector wavelengths : 272 nm.
- 4.2.3.4. Volume suntikan : 10 μ L.
Injection volume : 10 μ L.
- 4.2.3.5. Pelarut : Metanol : Dapar (65 : 35).
Solvent Methanol : Buffer (65 : 35)
- 4.2.3.6. Fase gerak : Metanol : Dapar (65 : 35).
Mobile phase Methanol : Buffer (65 : 35)
- 4.2.3.7. Waktu Retensi : 2.0 $\pm$ 2 menit
Retention Time : 2.0 $\pm$ 2 minutes
- 4.2.3.8. End Time : 5.0 $\pm$ 2 menit
End Time : 5.0 $\pm$ 2 minutes
- 4.2.3.9. RSD : $\leq$ 0,85% (Larutan standar)
RSD : $\leq$ 0.85% (Standard solution)

4.2.4. Pembuatan Larutan Dapar
Preparation of Buffer solution

- 4.2.4.1. Timbang saksama 6.8 g Potassium dihydrogen phosphate (KH_2PO_4)
Weigh accurately 6.8 g of Potassium Dihydrogen Phosphate (KH_2PO_4).
- 4.2.4.2. Masukkan ke dalam gelas piala 1000 mL.
Put into beaker glass 1000 mL.
- 4.2.4.3. Tambahkan 500 mL purified water, aduk sampai larut.
Add 500 mL of purified water, stir until dissolve
- 4.2.4.4. Tambahkan purified water sampai tanda batas, aduk sampai homogen.
Add purified water up to volume, stir until homogeneous

4.2.5. Larutan standar (Konsentrasi : 0.1 mg/mL)
Standard solution (Concentration : 0.1 mg/mL)

- 4.2.5.1. Timbang seksama 50.0 mg Methylparaben WS.
Weigh accurately 50.0 mg Methylparaben WS
- 4.2.5.2. Masukkan ke dalam labu ukur 50 mL.
Put into volumetric flask 50 mL.
- 4.2.5.3. Tambahkan 2,5 mL metanol, sonikasikan selama 10 menit.
Add 2.5 mL of methanol, sonicate for 10 minutes
- 4.2.5.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
Add solvent up to volume, mix until homogeneous
- 4.2.5.5. Pipet 10 mL larutan, masukkan ke dalam labu ukur 100 mL.
Pipette 10 mL of solution, put into volumetric flask 100 mL
- 4.2.5.6. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.



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FP uji = Faktor pengenceran larutan uji (500)
Dilution factor of test solution (500)
FP std = Faktor pengenceran larutan standar (500)
Dilution factor of standard solution (500)
F Kadar Working Standar (WS) dalam persen (%)
Working Standard (WS) content in percent (%)

4.3. Penetapan cemaran organik

Determination of Organic Impurity

4.3.1. Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku.
Requirement In accordance with applicable product specifications.

4.3.2. Metode : High Performance Liquid Chromatography
Method High Performance Liquid Chromatography

4.3.3. Kondisi pengerjaan HPLC
HPLC Operating Conditions

4.3.3.1. Kolom : Kolom XBridge C18 150 mm x 4.6 mm, 5 µm (L1).
Column C18 150 mm x 4.6 mm, 5 µm XBridge column (L1).

4.3.3.2. Laju alir : 1.3 mL/menit.
Flow rate 1.3 mL/minutes.

4.3.3.3. Panjang gelombang detektor : 272 nm.
Detector wavelengths 272 nm.

4.3.3.4. Suhu Kolom : 10 µL.
Column temperature 10 µL.

4.3.3.5. Pelarut : Metanol : Dapar (65 : 35).
Solvent Methanol : Buffer (65 : 35)

4.3.3.6. Fase gerak : Metanol : Dapar (65 : 35).
Mobile Phase Methanol : Buffer (65 : 35)

4.3.3.7. Run Time : 5 kali waktu retensi dari metilparaben
Run Time 5 times the retention time of methylparaben

4.3.3.8. Waktu Retensi : 1.8 ± 2 menit
Retention Time 1.8 ± 2 minutes

4.3.3.9. End Time : 9.0 ± 2 menit
End Time 9.0 ± 2 minutes

4.3.3.10. Resolusi : ≥ 2.0 antara puncak p-hydroxy benzoic acid dan metilparaben
(Larutan standar A)
Resolution ≥ 2.0 between the p-hydroxybenzoic acid and methylparaben peaks (Standard solution A)

**PROTOKOL TRANSFER METODE ANALISA
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4.2.3. Kondisi pengerjaan HPLC

HPLC Operating Conditions

- | | |
|-------------------------------------|--|
| 4.2.3.1. Kolom | : Kolom XBridge C18 150 mm x 4.6 mm, 5 µm (L1). |
| Column | : C18 150 mm x 4.6 mm, 5 µm XBridge column (L1). |
| 4.2.3.2. Laju alir | : 1.3 mL/menit. |
| Flow rate | : 1.3 mL/minutes. |
| 4.2.3.3. Panjang gelombang detektor | : 272 nm. |
| Detector wavelengths | : 272 nm. |
| 4.2.3.4. Volume suntikan | : 10 µL. |
| Injection volume | : 10 µL. |
| 4.2.3.5. Pelarut | : Metanol : Dapar (65 : 35). |
| Solvent | : Methanol : Buffer (65 : 35) |
| 4.2.3.6. Fase gerak | : Metanol : Dapar (65 : 35). |
| Mobile phase | : Methanol : Buffer (65 : 35) |
| 4.2.3.7. Waktu Retensi | : 4.0 ± 2 menit |
| Retention Time | : 4.0 ± 2 minutes |
| 4.2.3.8. End Time | : 7.0 ± 2 menit |
| End Time | : 7.0 ± 2 minutes |
| 4.2.3.9. RSD | : ≤ 0.85% (Larutan standar) |
| RSD | : ≤ 0.85% (Standard solution) |

4.2.4. Pembuatan Larutan Dapar

Preparation of Buffer solution

- | | |
|--|--|
| 4.2.4.1. Timbang saksama 6.8 g Potassium dihydrogen phosphate (KH ₂ PO ₄) | |
| Weigh accurately 6.8 g of Potassium Dihydrogen Phosphate (KH ₂ PO ₄). | |
| 4.2.4.2. Masukkan ke dalam gelas piala 1000 mL. | |
| Put into beaker glass 1000 mL. | |
| 4.2.4.3. Tambahkan 500 mL purified water, aduk sampai larut. | |
| Add 500 mL of purified water, stir until dissolve | |
| 4.2.4.4. Tambahkan purified water sampai tanda batas, aduk sampai homogen. | |
| Add purified water up to volume, stir until homogeneous | |

4.2.5. Larutan standar (Konsentrasi : 0.1 mg/mL)

Standard solution (Concentration : 0.1 mg/mL)

- | | |
|--|--|
| 4.2.5.1. Timbang seksama 50.0 mg Propilparaben WS. | |
| Weigh accurately 50.0 mg Propylparaben WS | |
| 4.2.5.2. Masukkan ke dalam labu ukur 50 mL. | |
| Put into volumetric flask 50 mL. | |
| 4.2.5.3. Tambahkan 2.5 mL metanol, sonikasikan selama 10 menit. | |
| Add 2.5 mL of methanol, sonicate for 10 minutes | |
| 4.2.5.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. | |
| Add solvent up to volume, mix until homogeneous | |
| 4.2.5.5. Pipet 10 mL larutan, masukkan ke dalam labu ukur 100 mL. | |
| Pipette 10 mL of solution, put into volumetric flask 100 mL. | |
| 4.2.5.6. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. | |
| Add solvent up to volume, mix until homogeneous | |
| 4.2.5.7. Saring larutan menggunakan syringe filter PTFE 0.45 µm. | |
| Filter solution with syringe filter PTFE 0.45 µm. | |

Rencana Pengujian Bahan Baku Metilparaben dan Propilparaben 2026													
No.	Nama Bahan Baku	Bulan											
		Jan	Feb	Mar	Apr	Mei	Jun	Jul	Aug	Sep	Okt	Nov	Des
1	Metilparaben	-	-	-	-	1	1	-	1	-	-	-	-
2	Propilparaben	-	-	1	-	-	1	-	-	-	-	-	-

No	Nama Bahan Baku	Kolom	Kedatangan	Parameter	Total injekan per kedatangan	Total injekan	
1	Methylparaben	XBridge C18 150 mm x 4,6 mm, 5 um (L1)	3	Penetapan Kadar	9	27	
				Cemaran Organik	14	42	
2	Propylparaben		2	Penetapan Kadar	9	18	
				Cemaran Organik	14	28	
Total						115	
(+) worstcase 30%						149,5	

Total injekan 2026

150 injekan

Estimasi ketahanan 1 kolom

500 injekan

Kebutuhan kolom 2026

$150/500 = 0.3$ dibulatkan menjadi 1 kolom


PT Kromtekindo Utama

Jl. RC Veteran 3,Bintaro
 Jakarta Selatan, 12330
 Phone : 021 7373043 , 7373031
 No.
 Fax :
 Email : support@kromtekindo.co.id
 Website : www.kromtekindo.com

Kepada Yth,
 MERSIFARMA TIRMAKU MERCUSANA,PT
 JL. RAYA PELABUHAN KM. 18 CIKEMBAR KAB. SUKABUMI, JAWA BARAT

T :
 F :
 M :
 Up IBU DINDA

For :

dinda.bahri@mersifarma.com

QUOTATION	
No.	: SQC/KU/26/III/016
Date	: Mar 3, 2026

No.	Part No.	Description	Qty	Unit Price	Persentase Discount %	Line Discount	Unit Price After Discount	Total Price
1	186003116	XBridge C18 5µm 4.6x150mm Column	1	29.736.000,00	20	5.947.200	23.788.800	23.788.800,00
Subtotal							23.788.800,00	
VAT Amount							2.616.768,00	
Total RP Incl. VAT							26.405.568,00	

Note:

1. Condition of Goods : STOCK
2. Payment Term : 30 DAYS
3. TOP Note : HARGA SEWAKTU-WAKTU DAPAT BERUBAH (Sesuai Kurs yang berlaku)
4. Validity Quote to Date : 06 March 2026

Dea Gresia Dolok Saribu
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Suciani Gustina