

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 Pemeriksaan Residual Solvent Methanol bahan baku Sucralose	Js	0	1	-1	0	1	0	0
2	IMO10028	Jasa Analisa Parameter Limit of Hydrolisis bahan baku Sucralose	Js	0	1	-1	0	1	0	0

Catatan :

- Penggunaan jasa untuk pemenuhan pemeriksaan **Residual Solvent Methanol dan Limit of Hydrolisis** pada bahan baku Sucralose dengan No. Batch:
1. U126021608 Ex. Unitech Chemicals (Zibo)
- Estimasi harga Residual solvent metanol : Rp.427.350
- Estimasi harga Limit of Hydrolisis : Rp 700.000

Latar belakang permintaan:

- Parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan belum terdapat metode yang tervalidasi di PT. Mersifarma dan belum dilakukan TMA kepada Dept. QC
- Sebagai pemenuhan regulasi terhadap parameter analisa bahan baku untuk perilsan kedatangan awal.
- Analisa pemeriksaan Residual solvent metanol menggunakan metode GC-FID dengan headspace sampler dan belum tersedia kolom G16 0.32 mm x 30 m; 1.0µm
- Analisa Parameter Limit of Hydrolisis menggunakan metode Kromatografi lapis tipis namun belum tersedia ragen p-anisidine dan reagen phtalic acid
- **Terlampir USP terkini, CoA bahan baku dan penawaran harga.**

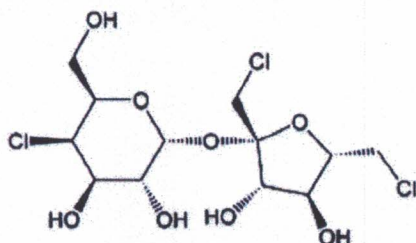
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Mengetahui


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Sucralose



$C_{12}H_{19}Cl_3O_8$ 397.63
1,6-Dichloro-1,6-dideoxy- β -D-fructofuranosyl-4-chloro-4-deoxy- α -D-galactopyranoside;
1',4,6'-Trichlorogalactosucrose CAS RN®: 56038-13-2.

DEFINITION

Sucralose contains NLT 98.0% and NMT 102.0% of sucralose ($C_{12}H_{19}Cl_3O_8$), calculated on the anhydrous basis.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K
- B.** The retention time of the principal peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- C.** The R_f value of the principal spot of the *Sample solution* corresponds to that of *Standard solution A*, as obtained in the test for *Related Compounds*.

ASSAY

Change to read:

PROCEDURE

Mobile phase: Acetonitrile and water (3:17)
Standard solution: 1 mg/mL of USP Sucralose RS in *Mobile phase*

Sample solution: 1 mg/mL of Sucralose in *Mobile phase*

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

Mode: LC

Detector: Refractive index

Column: 8-mm $\times$ 10-cm; $5\text{-}\mu\text{m}$ Δ (NF 1-Dec-2023) packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time of sucralose is about 9 min.]

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sucralose ($C_{12}H_{19}Cl_3O_8$) in the portion of Sucralose taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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

r_S = peak response of sucralose from the *Standard solution*

C_S = concentration of USP Sucralose RS in the *Standard solution* (mg/mL)

C_U = concentration of Sucralose in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- RESIDUE ON IGNITION** (281): NMT 0.7%

Change to read:

LIMIT OF METHANOL

Standard stock solution: 1000 $\mu\text{g/mL}$ of methanol in water

Standard solution: Transfer 1.000 g of Sucralose to a 22-mL headspace vial. Add 4.0 mL of 10% (w/v) sodium chloride solution. Add 1.00 mL of the *Standard stock solution*. Crimp a cap with a Teflon seal tightly onto the vial, and mix the solution well.

Sample solution: Add 1.000 g of Sucralose to a 22-mL headspace vial. Add 4.0 mL of a 10% (w/v) sodium chloride solution. Add 1.00 mL of water. Crimp a cap with a Teflon seal tightly onto the vial, and mix the solution well.

Chromatographic system

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

Mode: GC with balanced-pressure headspace sampler

Detector: Flame ionization

Column: 0.32-mm $\times$ 30-m; 1.0- μm layer of phase G16

Temperatures

Injection port: 110°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	0	50	3
50	10	80	0
80	50	230	10

Carrier gas: Helium

Headspace sampler

[NOTE—The capillary column is installed through the GC inlet and through the transfer line to give on-column injection.]

Temperatures

Equilibration: 90°

Needle: 100°

Transfer line: 110°

Times

Equilibration: 10 min

Pressurization: 3.0 min

Withdrawal: 0.5 min

Injection: 0.15 min

Cycle: 25 min

Sampler delivery system: Helium set at 90 psi (not to exceed 100 psi)

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 10.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methanol in the portion of Sucralose taken:

$$\text{Result} = (r_U \times W_S) / [(r_S - r_U) \times W_U] \times 100$$

r_U = peak area of methanol from the *Sample solution*

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W_s = weight of methanol in the *Standard solution* (g)
 r_s = peak area of methanol from the *Standard solution*
 W_u = weight of Sucralose to prepare the *Sample solution* (g) [▲] (NF 1-Dec-2023)

Acceptance criteria: NMT 0.1%

• **RELATED COMPOUNDS**

Adsorbent: 0.20-mm layer of octadecylsilanized chromatographic silica gel. The thin-layer chromatographic plate also has a preadsorbent zone.

Detection reagent: Sulfuric acid in methanol (3 in 20)
Standard solution A: 10.0 mg/mL of USP Sucralose RS in methanol

Standard solution B: 0.5 mL of *Standard solution A* diluted with methanol to 10.0 mL

Sample solution: 100.0 mg/mL of Sucralose in methanol
Developing solvent system: Acetonitrile and sodium chloride solution (1 in 20) (3:7)

Application volume: 5 μ L

Analysis

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

Proceed as directed under *Chromatography* (621), *Thin-Layer Chromatography*. Spray the plate with *Detection reagent*. Heat the plate for 10 min at 125°.

Acceptance criteria: The R_f value of the principal spot from the *Sample solution* corresponds to that obtained from *Standard solution A*, and the color of any other single spot from the *Sample solution* is not more intense than that of the principal spot from *Standard solution B* (0.5%).

Change to read:

• **LIMIT OF HYDROLYSIS PRODUCTS**

[NOTE—This test does not require a developing solvent.]

Adsorbent: 0.25-mm layer of chromatographic silica gel
Spray reagent: 12.3 mg/mL of *p*-anisidine and 16.6 mg/mL of phthalic acid in methanol. Store the solution in the dark

and refrigerate to prevent discoloration. Discard if the solution becomes discolored. [**CAUTION**—*p*-Anisidine is toxic if inhaled or if absorbed through the skin.]

Standard solution A: 100 mg/mL of mannitol

Standard solution B: 0.4 mg/mL of fructose and 100 mg/mL of mannitol

Sample solution: 250 mg/mL of Sucralose in methanol

Application volume: 5- μ L portions separately applied in 1- μ L increments, allowing the plate to dry between applications

Analysis

Samples: [▲]*Standard solution A*, *Standard solution B*, [▲] (NF 1-Dec-2023) and *Sample solution*

Proceed as directed under *Chromatography* (621),

Thin-Layer Chromatography. Spray the plate with *Spray reagent*, and heat the plate at 100 $\pm$ 2° for 15 min. If the spot from *Standard solution A* has darkened, repeat the test, heating for a shorter period of time. Immediately after heating, view the plate against a dark background.

Acceptance criteria: The color of the spot from the *Sample solution* is not more intense than that from *Standard solution B* (0.1%).

SPECIFIC TESTS

Change to read:

- **OPTICAL ROTATION** (781S), *Procedures, Specific Rotation*
Sample solution: 10 mg/mL of Sucralose[▲], calculated on the anhydrous basis [▲] (NF 1-Dec-2023)
Acceptance criteria: +84.0° to +87.5° at 20°
- **WATER DETERMINATION** (921), *Method I*: NMT 2.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, in a cool, dry place, at a temperature not exceeding 21°.
- **USP REFERENCE STANDARDS** (11)
USP Sucralose RS



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CERTIFICATE OF ANALYSIS

Product	Sucralose	Quantity	100kg	Test date	2026-02-18
Batch NO.	U126021608 ✓	Manufacture date	2026-02-16	Expired date	2028-02-15 ✓

TESTED RESULTS

ITEM	STANDARD	RESULT
Identification A(IR)	Infrared spectra of standard and sample should meet each other	Pass
Identification B (Retention time of HPLC)	The retention time of the principal peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Pass
Identification C(By TLC)	The R_f value of the major spot in the thin-layer chromatogram of the Product Preparation is the same as that of the Standard Preparation obtained in the test for Related Substances.	Pass
Appearance	White powder	Pass
Particle Size (80 mesh),%	≥95	Pass
Assay, %	98.0~102.0	99.84
Specific Rotation, °	+84.0~+87.5	+86.2
Moisture, %	≤2.0	0.1
PH (10% aqueous solution)	5.0-7.0	5.62
Ignited Residue, %	≤0.7	0.1
Methanol, %	≤0.1	0.01
Heavy Metals (as lead) ,mg/kg	≤10	<10
Arsenic(As),mg/kg	≤3	Not Detected
Lead,mg/kg	≤1	Not Detected
Triphenylphosphine Oxide,mg/kg	≤150	<150
Hydrolysis Products, %	≤0.1	Pass
Related Substances, %	≤0.5	Pass
Total Aerobic count, cfu/g	≤250	10
Yeasts & moulds, cfu/g	≤50	10
Coliform, MPN/g	≤3.0	<0.3
E.coli	Negative	Negative
S.aureus	Negative	Negative
Salmonella	Negative	Negative
Storage condition	Store in well closed container, in dry and cool place, at a temperature not exceeding 21℃.	
Conclusion	The quality in conformity with the E-955/USP 43 / FCC 12	
Inspector: Liu Xiangyang	Checked: Sun Jinxia	Approved: Tang Xianghui

No. : 438/XI/MEF/24

Jakarta, 22 November 2024

Hal : Penawaran harga uji Sucralose

Kepada Yth.

Ibu Julfriaeni

PT. Mersifama

Bersama ini kami sampaikan penawaran harga untuk pengujian yang diminta sebagai berikut :

No.	Sampel	Pengujian	Metode Analisis	Reference	Jumlah sampel	Biaya (Rp) Exclude PPN
1	Sucralose	Batas Hidrolisis	TLC	USP 2023	10 gram	Rp 700.000 (14 HK)
2		Related Compound	TLC	USP 2023	10 gram	Rp 700.000 (14 HK)

Term dan kondisi :

1. Lama waktu analisa sampel dihitung sejak sampel dan PO diterima Pihak Omega
2. Mohon informasikan kandungan analit (jika sampel produk jadi) jika tidak ada di label
3. Pengujian akan dikerjakan setelah sampel dan PO kami terima.
4. Penagihan akan dilakukan berdasarkan jumlah sampel/PO yang diterima.
5. Sertakan juga placebo untuk pertama kali pengujian/perubahan formula sejumlah 20 g
6. Cara pembayaran 100% setelah hasil Analisa dan invoice diterima
7. Penawaran berlaku untuk masa 1 (satu) bulan sejak tanggal penawaran

Demikian penawaran ini kami sampaikan, mohon PO dapat dikirimkan melalui email ke admin@omegaresearch.id dan finance@omegaresearch.id

Atas perhatiannya kami ucapkan terima kasih.

Hormat kami,
PT Omega Medika Farma Laboratori



Regita Pramesti
Marketing



Kepada Yth
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Nomor Penawaran : SIG.MARK.PN.I.2025.001797
Tanggal : 14 January 2025

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

1. Bahan Baku

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

BIAYA PENGUJIAN (IDR)	
Subtotal	385,000
PPN (11%)	42,350
Total	427,350

Catatan

- Dilampirkan surat penawaran ini saat pengiriman sampel pengujian
- Sampel yang dibutuhkan minimal 50g atau 50ml persampelnya
- Lama pengujian Reguler/Normal adalah 8 hari kerja

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Pelanggan diharap melakukan pembayaran uang muka sebesar 50% dari total biaya pengujian dan pelunasan sebelum tanggal estimasi uji selesai melalui transfer ke rekening :

Nama Bank : Bank Mandiri, Cabang Juanda
Atas Nama : PT. Saraswanti Indo Genetech
No. Rekening : 133.000.1160.811

Kirimkan bukti pembayaran ke email sales terkait dan atau paymentinfo-sig@saraswanti.com dan harap lampirkan surat penawaran saat proses memasukkan sampel

Harga yang tercantum pada surat penawaran berikut dapat berubah sewaktu-waktu tanpa pemberitahuan terlebih dahulu dan hanya berlaku untuk sampel sesuai pada surat penawaran.

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

Hormat Kami,
PT. Saraswanti Indo Genetech

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Catatan Tambahan

Towards
a safer world

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