

Bagian: QC

Due Date : 02 Nov 2026

Tanggal : 16 Sep 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	IMO11439	Kolom Ultisil (5µm) 4.6 x 250 mm	Pc	0	5	-5	0	5	0	0

Catatan :

Kolom Ultisil XB - C18, 5µm, 4.6 x 250 mm Ex. Welch Part. No : H00201-31043

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewatkan sampel menggunakan fase gerak melalui kolom.
- Kolom tersebut digunakan untuk penetapan kadar produk Ketorolac Injeksi 30 mg/mL dan Mersitropil Infus Intravena 12 g/60 mL.
- Estimasi harga : Rp.5.200.000 / unit.
- Pemesanan terakhir pada bulan Mei 2026 (PF000972).

Latar Belakang Permintaan :

- Sehubungan dengan adanya transfer metode analisa penetapan kadar produk Ketorolac Injeksi 30 mg/mL dan Mersitropil Infus Intravena 12 g/60 mL. maka diperlukan pembelian kolom sesuai dengan metode yang telah dikembangkan oleh Dept. R&D, sehingga dapat dilakukan pengujian rutin untuk produk tersebut.

Terlampir metode analisa, rencana kebutuhan dan penawaran harga.

Dibuat


ADA 16/9/26

Mengetahui


16/09/26

 Good Quality Improves Life's Quality PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISA IDENTIFIKASI, KADAR DAN CEMARAN DALAM KETOROLAK INJEKSI SECARA HPLC TRANSFER PROTOCOL METHOD ANALYSIS OF IDENTIFICATION, ASSAY AND IMPURITY IN KETOROLAC INJECTION BY HPLC	Halaman : Page 3 of 14 Pages No. Dokumen : RD.02-PTP/084.00 Document Number Tanggal Dokumen : Disetujui : Document Approved Date Menggantikan No. : - Replaces No.
	3.4.3. Menjamin bahwa semua bahan yang digunakan untuk transfer metode analisa termasuk reagensia dan baku pembanding belum kedaluwarsa. <i>Ensuring that all materials used for the transfer method analysis including reagents and reference standards have not expired.</i> 3.4.4. Melaksanakan transfer metode analisa sesuai dengan protokol. <i>Carry out the transfer of analytical methods in accordance with the protocol.</i> 3.4.5. Mencatat semua hasil uji dalam format yang telah disediakan. <i>Record all test results in the format provided.</i> 3.4.6. Mengawasi pelaksanaan, memeriksa kebenaran dan kelengkapan catatan pengujian. <i>Supervise implementation, check the correctness and completeness of test records.</i> 3.4.7. Melaporkan pelaksanaan dan penyimpangan yang ditemui selama pelaksanaan transfer metode analisa bahan baku, bahan kemasan, obat jadi dan residu pembersihan. <i>Report the implementation and deviations encountered during the transfer of analytical methods for raw materials, packaging materials, finished drugs and cleaning residues.</i> 3.4.8. Menyusun protokol dan laporan transfer metode analisa. <i>Prepare protocols and reports on transfer of analytical methods.</i> 3.5. <i>Quality Control Spv/Staf and Analyst</i> <i>Quality Control Spv/Staf and Analyst</i> 3.5.1. Menjamin semua alat/instrumen yang digunakan untuk transfer metode analisa telah dikalibrasi. <i>Ensure that all tools and instruments used for transfer method analysis are calibrated.</i> 3.5.2. Menjamin bahwa semua bahan yang digunakan untuk transfer metode analisa termasuk reagensia dan baku pembanding belum kedaluwarsa. <i>Ensuring that all materials used for the transfer method analysis including reagents and reference standards have not expired.</i> 3.5.3. Melaksanakan transfer metode analisa sesuai dengan protokol. <i>Carry out the transfer of analytical methods in accordance with the protocol.</i> 3.5.4. Mencatat semua hasil uji dalam format yang telah disediakan. <i>Record all test results in the format provided.</i> 3.5.5. Mengawasi pelaksanaan, memeriksa kebenaran dan kelengkapan catatan pengujian. <i>Supervise implementation, check the correctness and completeness of test records.</i> 3.5.6. Melaporkan pelaksanaan dan penyimpangan yang ditemui selama pelaksanaan transfer metode analisa bahan baku, bahan kemasan, obat jadi dan residu pembersihan. <i>Report the implementation and deviations encountered during the transfer of analytical methods for raw materials, packaging materials, finished drugs and cleaning residues.</i> 3.5.7. Menyusun protokol dan laporan transfer metode analisa. <i>Prepare protocols and reports on transfer of analytical methods.</i>	
4. METODE PENGUJIAN ANALYSIS METHOD		
4.1. Nama Produk Branded : Ketoxi Injeksi 30 mg/mL <i>Branded Product Name Ketoxi Injection 30 mg/mL</i> 4.2. Nama Produk Generik : Ketorolak Injeksi 30 mg/mL <i>Generic Product Name Ketorolac Injection 30 mg/mL</i> 4.3. Bahan Aktif : Ketorolak Trometamin <i>Active Ingredient Ketorolac Tromethamine</i> 4.4. Komposisi : Tiap ml injeksi mengandung Ketorolak 30 mg <i>Composition Each ml contains 30 mg Ketorolac.</i>		

 Good Quality Improves Life's Quality PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISA IDENTIFIKASI, KADAR DAN CEMARAN DALAM KETOROLAK INJEKSI SECARA HPLC TRANSFER PROTOCOL METHOD ANALYSIS OF IDENTIFICATION, ASSAY AND IMPURITY IN KETOROLAC INJECTION BY HPLC	Halaman : Page 4 of 14 Pages No. Dokumen : RD.02-PTP/084.00 Document Number Tanggal Dokumen : Disetujui : Document Approved Date Menggantikan No. : - Replaces No.
4.5. Penetapan Kadar <i>Assay</i> 4.5.1. Persyaratan : 90,0 - 110,0 % <i>Requirement 90,0 - 110,0 %</i> 4.5.2. Metode : High Performance Liquid Chromatography <i>Method High Performance Liquid Chromatography</i> 4.5.3. Kondisi pengerjaan HPLC <i>HPLC Operating Conditions</i> 4.5.3.1. Kolom : Kolom Ultisil C18 250 mmx 4,6 mm 5 µm (L1). <i>Column Nomor Katalog: H00201-31043</i> : C18 60 250 mmx 4,6 mm 5 µm (L1), Catalog Number: H00201-31043, Ultisil column 4.5.3.2. Aliran pompa : 1,2 mL / menit <i>Flow Rate 1,2 mL / minute</i> 4.5.3.3. Panjang gelombang detektor : PDA 200-600 nm (254 nm) <i>Detector wavelength PDA 200-600 nm (254 nm)</i> 4.5.3.4. Volume penyuntikkan : 100 µL <i>Injection volume 100 µL</i> 4.5.3.5. Pelarut : Methanol : Purified water (1:1) <i>Solvent Methanol : Purified water (1:1)</i> 4.5.3.6. Fase gerak : Metanol : Purified Water : Asam Asetat Glisial (55 : 44 : 1) <i>Mobile phase Methanol : Purified Water : Glacial Acetic Acid (55 : 44 : 1)</i> 4.5.3.7. Waktu Retensi : 15 Menit ± 3 Menit <i>Retention Time 15 Minutes ± 3 Minutes</i> 4.5.3.8. Waktu Berakhir : 20 Menit ± 4 Menit <i>End Time 20 Minutes ± 4 Minutes</i> 4.5.4. Alat dan Bahan <i>Tools and Materials</i> 4.5.4.1. Labu tentukur Amber 50 mL <i>Amber volumetric flask 50 mL</i> 4.5.4.2. Labu tentukur Amber 25 mL <i>Amber volumetric flask 25 mL</i> 4.5.4.3. Pipet Mohr 10 mL <i>10 mL Mohr pipette</i> 4.5.4.4. Pipet volume 2 mL. <i>Volume pippete 2 mL.</i> 4.5.4.5. Timbangan <i>Scales</i> 4.5.4.6. Sonikator <i>Sonicator</i> 4.5.4.7. Methanol Ex. Fisher Brand No. Katalog : A452-4 <i>Methanol Ex. Fisher Brand Cat No. : A452-4</i> 4.5.4.8. Asam Asetat Glisial ex. RCI, Nomor Katalog. AR1002 <i>Acetic Acid Glacial ex. RCI, Catalog Number. AR1002</i> 4.5.5. Pembuatan Larutan Induk Standar [0,6 mg/mL] <i>Preparation of Standard Stock Solution [0.6 mg/mL]</i>		

 Good Quality Improves Life's Quality PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISA IDENTIFIKASI, KADAR DAN CEMARAN DALAM KETOROLAK INJEKSI SECARA HPLC TRANSFER PROTOCOL METHOD ANALYSIS OF IDENTIFICATION, ASSAY AND IMPURITY IN KETOROLAC INJECTION BY HPLC	Halaman : Page 5 of 14 Pages No. Dokumen : RD.02-PTP/084.00 Document Number Tanggal Dokumen : Disetujui Document Approved Date Menggantikan No. : Replaces No.
	4.5.5.1. Timbang seksama 30,0 mg Ketorolak trometamin WS, masukkan ke dalam labu ukur 50 mL. <i>Weigh accurately 33.0 mg Ketorolac Tromethamine WS, put into 50 mL volumetric flask.</i> 4.5.5.2. Tambahkan 25 mL pelarut, sonikasikan 10 menit. <i>Add 25 mL of solvent, sonicate for ± 10 minutes.</i> 4.5.5.3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.6. Pembuatan Larutan Standar [0.048 mg/mL] <i>Preparation of Standard solution [0.048 mg/mL]</i> 4.5.6.1. Pipet 2.0 mL Larutan Induk Standar, masukkan ke dalam labu ukur 25 mL. <i>Pipette 2.0 mL of Standard Stock Solution, transfer to volumetric flask 25 mL.</i> 4.5.6.2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.6.3. Saring larutan menggunakan syringe filter PTFE 0.45 µm. <i>Filter the solution using a 0.45 µm PTFE syringe filter.</i> 4.5.6.4. Masukkan ke dalam vial HPLC. <i>Put it into HPLC vial.</i> 4.5.7. Pembuatan Larutan sampel [0.048 mg/mL] <i>Preparation of Sample solution [0.048 mg/mL]</i> 4.5.7.1. Pipet 1.0 mL larutan Injeksi Ketorolak Trometamin 30 mg / mL setara dengan 30.0 mg Ketorolak Trometamin, masukkan ke dalam labu ukur 50 mL. <i>Pipette 1.0 mL Ketorolac Tromethamine Injection 30 mg / mL equivalent with 30.0 mg Ketorolac Tromethamine, put into 50 mL volumetric flask.</i> 4.5.7.2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.7.3. Pipet 2.0 mL larutan, masukkan ke dalam labu ukur 25 mL. <i>Pipette 2.0 mL of solution, transfer to volumetric flask 25 mL.</i> 4.5.7.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.7.5. Saring larutan menggunakan syringe filter PTFE 0.45 µm. <i>Filter the solution using a 0.45 µm PTFE syringe filter.</i> 4.5.7.6. Masukkan ke dalam vial HPLC. <i>Put it into HPLC vial.</i>	
	4.5.8. Pembuatan Larutan placebo <i>Preparation of Placebo solution</i> 4.5.8.1. Pipet 1.0 mL larutan placebo, masukkan ke dalam labu ukur 50 mL. <i>Pipette 1.0 mL placebo solution, put into 50 mL volumetric flask.</i> 4.5.8.2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.8.3. Pipet 2.0 mL larutan, masukkan ke dalam labu ukur 25 mL. <i>Pipette 2.0 mL of solution, transfer to volumetric flask 25 mL.</i> 4.5.8.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, mix homogeneously.</i> 4.5.8.5. Saring larutan menggunakan syringe filter PTFE 0.45 µm. <i>Filter the solution using a 0.45 µm PTFE syringe filter.</i>	

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4.5.8.6. Masukkan ke dalam vial HPLC. <i>Put it into HPLC vial.</i> 4.5.9. Uji Kesesuaian Sistem : <i>System suitability test</i> 4.5.9.1. Suntikkan larutan standar ke sistem HPLC sebanyak 6 kali. <i>Inject standard solution into HPLC for 6 times replication.</i> 4.5.9.2. Amati respons dan hitung RSD dari hasil perhitungan alat. <i>Determine peak areas and calculate RSD out of each instrument responds.</i> Kriteria keberterimaan : RSD luas area ≤ 1,0% Acceptance criteria : RSD area ≤ 1,0% RSD waktu retensi : ≤ 1,0 % RSD retention time ≤ 1,0% Tailing Ketorolak ≤ 1,5 Tailing Ketorolac ≤ 1,5 4.5.10. Prosedur <i>Procedure</i> Suntikkan secara terpisah pelarut, larutan standar, dan larutan sampel ke dalam sistem HPLC. ukur respons puncak utama. <i>Separately inject solvent, standard solution, sample solution, System suitability solution into HPLC system, measure the major peak response.</i> <table data-bbox="1352 839 1971 1091"> <tr> <th>No</th><th>Larutan Solution</th><th>Jumlah injek Number of Injections</th></tr> <tr> <td>1.</td><td>Pelarut Solvent</td><td>1x</td></tr> <tr> <td>2.</td><td>Standar Standard</td><td>6x</td></tr> <tr> <td>3.</td><td>Sampel Sample</td><td>6x</td></tr> <tr> <td>4.</td><td>Placebo Placebo</td><td>1x</td></tr> </table> 4.5.11. Perhitungan <i>Calculation</i> Hitung perolehan kembali (%) Ketorolak Trometamin dalam cairan injeksi Ketorolak Trometamin 30 mg / mL dengan rumus : <i>Calculate the recovery (%) of Ketorolac Tromethamine in 30 mg/mL Ketorolac Tromethamine injection liquid according to the formula:</i> $\% \text{ Ketorolac Trometamol} = \frac{R_{\text{spl}} \times W_{\text{std}} \times FP_{\text{spl}}}{R_{\text{std}} \times V_{\text{spl}} \times 30 \times FP_{\text{std}}} \times F$ Keterangan : Information R spl = Respons puncak larutan sampel <i>Peak areas of sample solution</i> R std = Respons puncak larutan standar <i>Peak areas of standard solution</i> W std = Bobot standar yang ditimbang (mg) <i>Amount of standard Ketorolac tromethamine (mg)</i>	No	Larutan Solution	Jumlah injek Number of Injections	1.	Pelarut Solvent	1x	2.	Standar Standard	6x	3.	Sampel Sample	6x	4.	Placebo Placebo	1x		
No	Larutan Solution	Jumlah injek Number of Injections															
1.	Pelarut Solvent	1x															
2.	Standar Standard	6x															
3.	Sampel Sample	6x															
4.	Placebo Placebo	1x															

METODE ANALISA PRODUK
MERSITROPIL® INFUS INTRAVENA
12 g/60 mL
PRODUCT ANALYSIS METHOD
MERSITROPIL® INTRAVENOUS
INFUSION 12 g/60 mL

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Add 5–10 drops of 1 N Sodium Hydroxide solution, and shake until homogeneous.

- 6.1.4.4. Amati warna yang terbentuk dan perubahan warna yang terjadi.
Observe the colors that form and the color changes that occur.

6.2. Identifikasi 2

Identification 2

Bandingkan waktu retensi puncak utama kromatogram larutan sampel dengan larutan standar seperti diperoleh pada penetapan kadar.

Compare the retention times of the main peaks in the chromatograms of the sample solution with those of the standard solution, as obtained in the assay.

7. PENETAPAN KADAR⁽¹⁾

ASSAY⁽¹⁾

Persyaratan : Sesuai dengan spesifikasi produk yang berlaku
Requirement Meets the requirements for product specification
Metode : Kromatografi Cair Kinerja Tinggi (KCKT)
Method High Performance Liquid Chromatography (HPLC)

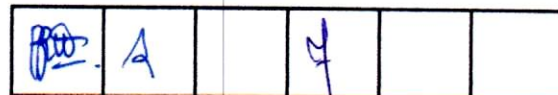
7.1. Alat dan Bahan

Tools and Materials

7.1.1. Alat

Tools

- 7.1.1.1. KCKT merek Waters Alliance Type e2695.
HPLC brand Waters Alliance Tipe e2695.
- 7.1.1.2. Timbangan digital.
Digital scale.
- 7.1.1.3. Kolom Ultisil XB-C18 250 mm x 4.6 mm, 5 µm (L1) Part No. H00201-31043.
Ultisil XB-C18 Column, 250 mm x 4.6 mm, 5 µm (L1), Part No. H00201-31043.
- 7.1.1.4. Vortex.
Vortex.
- 7.1.1.5. Pipet volumetrik 1 mL.
1 mL volumetric pipette.
- 7.1.1.6. Pipet volumetrik 5 mL.
5 mL volumetric pipette.
- 7.1.1.7. Labu ukur 10 mL.
10 mL volumetric flask.



**METODE ANALISA PRODUK
MERSITROPIL® INFUS INTRAVENA
12 g/60 mL
PRODUCT ANALYSIS METHOD
MERSITROPIL® INTRAVENOUS
INFUSION 12 g/60 mL**

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Keterangan:

Description

- Rspl : Respons puncak Piracetam dalam larutan sampel
Peak response of Piracetam in the sample solution
- Rstd : Respons puncak Piracetam dalam larutan standar
Peak response of Piracetam in a standard solution
- Wstd : Bobot WS Piracetam yang ditimbang dalam larutan standar (mg)
Mass of Piracetam WS weighed in the standard solution (mg)
- Vspl : Volume sampel yang dipipet dalam larutan sampel (mL)
Volume of sample pipetted into the sample solution (mL)
- 200 : Kandungan Piracetam per mL
Amount of Piracetam per mL
- FPspl : Faktor pengenceran Piracetam dalam larutan sampel (2000)
Dilution factor for Piracetam in the sample solution (2000)
- FPstd : Faktor pengenceran Piracetam dalam larutan standar (100)
Dilution factor for Piracetam in standard solutions (100)
- F : Kadar WS Piracetam dalam as is (%)
Piracetam WS assay as is (%)

8. SENYAWA SEJENIS⁽¹⁾

RELATED SUBSTANCES⁽¹⁾

- Persyaratan : Sesuai dengan spesifikasi produk yang berlaku
Requirement Meets the requirements for product specification
- Metode : Kromatografi Cair Kinerja Tinggi (KCKT)
Method High Performance Liquid Chromatography (HPLC)

Alat, bahan, dan kondisi pengerjaan KCKT lakukan seperti pada penetapan kadar.

The equipment, materials, and working conditions for HPLC should be the same as those used for assay.

- Waktu berakhir : 3x waktu retensi Piracetam
End time 3x retention times Piracetam

8.1. Pembuatan Larutan Standar (0.005 mg/mL)

Preparation of a Standard Solution (0.005 mg/mL)

Gunakan larutan induk standar (1 mg/mL) sesuai dengan penetapan kadar.

Use the standard stock solution (1 mg/mL) as specified for the assay.

	1				
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Rencana Penggunaan Kolom Ultisil 250 x 4,6 mm; 5 µm (C18)

No	Nama Produk	Parameter	Sisa Forecast 2026 (Batch)	Pengujian Stabilita (Interval)	Total Injekan (kali)	Kebutuhan Total (Injekan)
1	Ketorolak Injeksi Injeksi 30 mg / mL	Kadar dan Cemaran	60	12	25	1800
Total (mg)						1800

Kesimpulan : Dibutuhkan sebanyak 1800 / 500 injekan = 3,6 ~ **4 Kolom** Ultisil 250 x 4,6 mm; 5 µm (C18)

Only 1 left in stock! Get 10 mL Disposable HPLC Lab Syringe (100 pcs) now -- before anyone else!

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P/N: 1100201-31043
Ultisil XB-C18, 5µm, 4.6x250mm (1pcs/pk)
 Welch Materials, Inc.
 \$500.00 USD
 4 interest-free installments, or from \$45,13/mo with shop

Quantity: 1

Add to cart Buy with shop
 More payment options

Ultisil XB-C18 is one of the most versatile C18 analytical columns on the market. It features advanced bonding and double-endcapping technology, delivering nearly perfect peak shapes. This column is ideal for analyzing complex matrix samples and provides excellent peak shapes for acidic and basic compounds. It is particularly effective for the separation of traditional Chinese medicine compounds.

Quantity: 1 pcs/pk



Rencana Penggunaan Kolom Ultisil XB-C18, 5 μ m, 4.6 $\times$ 250 mm

No	Nama Produk	Parameter	Forecast 2026 (Batch)	Pengujian Stabilita (Interval)	Total Injeksi (kali)	Kebutuhan Total (Injeksi)
1	Mersitropil Infus Intravena 12 g / 60 mL	Kadar dan Senyawa Sejenis	2	1	17	51
Total (mg)						51

Kesimpulan : Dibutuhkan sebanyak 51 / 500 injeksi = 0,1 ~ 1 Kolom Ultisil XB-C18, 5 μ m, 4.6 $\times$ 250 mm



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Keywords ...



P/N: H0020T-31043

Ultisil XB-C18, 5 μ m, 4.6 $\times$ 250mm (1pcs/pk)

Welch Materials, Inc.

\$500.00 USD

4 interest-free installments, or from \$45,13/mo with [shop](#)

Quantity:

- 1 +

Add to cart



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Ultisil XB-C18 is one of the most versatile C18 analytical columns on the market. It features advanced bonding and double-endcapping technology, delivering nearly perfect peak shapes. This column is ideal for analyzing complex matrix samples and provides excellent peak shapes for acidic and basic compounds. It is particularly effective for the separation of traditional Chinese medicine compounds.

Quantity: 1 pcs/pk



PT. SURYA BUANA NUSANTARA

PT. SURYA BUANA NUSANTARA

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TEL : (62-21) 6470 3295; 640 6225

HP / WA : 0895-346039515

FAX : (62-21) 645 8467

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www.suryabuana.com

Company : PT Mersifarma Tirmaku Mercusana
Attn : Ibu Nabila Maretha
Title : Laboratorium
Re. : Informasi Harga

From : Sunarti
Page : 1 (including this page)
May 11, 2026
No. : 194/SBN/V/26-001/B

Quot

Dengan hormat,

Bersama ini perkenankanlah kami menyampaikan informasi harga sebagai berikut :

No	Description	Qty	Unit Price (Rp)	Total Price (Rp)
1	Ultisil 10µm XB-C18 120 Å, LC Column 250 x 4.6mm Welch Part Number : H00201-41043	1 Ea	5.400.000	5.400.000
2	Ultisil™ 5µm XB-C18 120 Å, LC Column 250 x 4.6mm Welch Part Number : H00201-31043	1 Ea	5.200.000	5.200.000

Keterangan :

- Harga Belum Termasuk PPN 11%
- Penyerahan : No. 1 Ready Stock, No.2 Indent 4-10 Minggu
- Pembayaran : 14 Hari
- Netto

Atas perhatiannya, kami ucapkan terima kasih.

Hormat kami,
Superti

PT. SURYA BUANA NUSANTARA

Our Partnership :



TOKYO CHEMICAL INDUSTRY



Ultron ES-OVM



INTEGRATED SALES