

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	IBS00082	Quetiapine Fumarate	mg	0	200	-200	0	200	0	0
2	IBS00352	Quetiapine Related Compound B	mg	0	25	-25	0	25	0	0
3	IBS00255	Quetiapine Related Compound G	mg	0	25	-25	0	25	0	0
4	IBS00350	Quetiapine System Suitability	mg	0	25	-25	0	25	0	0

Catatan :

1. Quetiapine Fumarate, Ex. USP, Cat. No : 1592704, CAS. No : 111974-72-2

- Digunakan sebagai baku pembanding untuk pembuatan larutan standar pada analisa pembakuan Working Standar Quetiapin Fumarat.
- Rencana kebutuhan sebanyak 32 mg. Pemesanan mengikuti MOQ, 1 Vial @200 mg.
- Estimasi harga : Rp.5.057.210 / Vial.

2. Quetiapine Related Compound B, Ex.Pharmaffiliates, Prod. Code : PA 17 02020, CAS. No : 111974-74-4**3. Quetiapine Related Compound G, Ex. Pharmaffiliates, Prod. Code : PA 17 02070, CAS. No : 3159-07-7**

- Digunakan sebagai standar untuk pembuatan larutan identifikasi puncak pada analisa cemaran organik bahan baku Quetiapin Fumarat.
- Rencana kebutuhan sebanyak 4 mg. Pemesanan mengikuti MOQ, 1 Vial @25 mg.

4. Quetiapine System Suitability, Ex. USP, Cat. No : 1592715

- Digunakan sebagai standar untuk pembuatan larutan kesesuaian sistem pada analisa kadar dan cemaran organik bahan baku Quetiapin Fumarat.
- Rencana kebutuhan sebanyak 20 mg. Pemesanan mengikuti MOQ, 1 Vial @25 mg.
- Estimasi harga : Rp.17.870.000 / Vial.

Latar Belakang Permintaan

- Sehubung dengan adanya transfer metode analisa penetapan kadar dan cemaran organik pada bahan baku Quetiapin Fumarat yang merupakan bahan baku baru maka dibutuhkan pengadaan Reference Standard tersebut sesuai dengan metode yang telah dikembangkan Dept. R&D, sehingga dapat dilakukan pengujian rutin untuk bahan baku tersebut.
- Pemesanan pertama kali Dept. QC.

Terlampir metode analisa, rencana kebutuhan dan penawaran harga.

Dibuat


.....

Mengetahui


.....

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 7 dari 28 7 of 28 Pages No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number
4. REFERENSI PROTOKOL TRANSFER METODE ANALISIS REFERENCE FOR THE ANALYTICAL METHOD TRANSFER PROTOCOL United States Pharmacopoeia - National Formulary 2026 monografi Quetiapine Fumarate. United States Pharmacopoeia - National Formulary 2026 monograph on Quetiapine Fumarate 5. JENIS TRANSFER METODE ANALISIS TYPE OF ANALYTICAL METHOD TRANSFER Jenis metode transfer yang digunakan adalah secara komparatif non-kolaboratif (langsung). The type of transfer method used is comparatively non-collaborative (direct). 6. METODE ANALISIS YANG DITRANSFER TRANSFERRED ANALYTICAL METHOD 6.1. Penetapan kadar secara KCKT. Assay by HPLC. 6.2. Cemaran organik secara KCKT. Organic impurity by HPLC. 7. PROSEDUR EKSPERIMENTAL EXPERIMENTAL PROCEDURE 7.1. Penetapan Kadar Assay 7.1.1. Alat dan Bahan Tools and Materials 7.1.1.1. Alat Tools 1. Timbangan merek Shimadzu Type AP 224 X. Scales brand Shimadzu Type AP 224 X. 2. KCKT merek Waters Alliance Type e2695. HPLC brand Waters Alliance Type e2695. 3. Kolom Zorbax RX-C8 250 x 4.6 mm, 5 µm (L7) ex Agilent Part No. 880967-901. 880975 - 906 Zorbax RX-C8 column, 250 x 4.6 mm, 5 µm (L7), ex Agilent, Part. No. 880967-901. 4. Sonikator. Sonicator. 5. pH meter. pH meter. 6. Vacuum. Vacuum.		

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 8 dari 28 8 of 28 Pages No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number
7. Gelas ukur 500 mL. 500 mL measuring cylinder. 8. Gelas ukur 100 mL. 100 mL measuring cylinder. 9. Labu ukur 5 mL. 5 mL volumetric flask. 10. Labu ukur 100 mL. 100 mL volumetric flask. 11. Labu ukur 10 mL. 10 mL volumetric flask. 12. Batang pengaduk. Stirring rod. 13. Kertas perkamen. Parchment paper. 14. Spatula. Spatula. 15. Kertas saring membran 0.22 µm. 0.22 µm nylon membrane filter. 16. Syringe filter 0.45 µm PTFE. PTFE 0.45 µm syringe filter. 17. Vial KCKT. HPLC vial. 7.1.1.2. Bahan Materials 1. WS Quetiapin Fumarat Quetiapine Fumarate WS 2. RS Kesesuaian Sistem Quetiapin ex USP Cat No. 1592715. Quetiapine System Suitability RS Cat No. 1592715. 3. Amonium Fosfat Dibasa ((NH₄)₂HPO₄) ex Supelco Cat No. 1 01207 0500. Dibasic Ammonium Phosphate ((NH₄)₂HPO₄) ex Supelco Cat No. 1 01207 0500. 4. Asam Fosfat (H₃PO₄) ex RCI Labscan Cat No. AR1152. Phosphoric Acid (H₃PO₄) ex RCI Labscan Cat No. AR1152. 5. Metanol ex Fisher Brand Cat No. A452-4. Methanol ex Fisher Brand Cat No. A452-4.		

 PT MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 11 dari 28 Pages : 11 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. :- Supersedes Number
	Place the weighing bottle in a desiccator, allowing it to reach room temperature before weighing. 12. Timbang bobot akhir botol timbang (C). Weigh the final weight of the weighing bottle (C). 13. Hitung persentase (%) susut pengeringan Quetiapin Fumarat, dengan menggunakan rumus berikut. Calculate the percentage (%) drying shrinkage of Quetiapine Fumarate, using the following formula. $\text{Loss on Drying (\%)} = \frac{(B-A) - (C-A)}{(B-A)} \times 100$ Keterangan: Descriptions A : Bobot botol timbang awal tanpa Quetiapin Fumarat (g) Initial weighing bottle weight without Quetiapine Fumarate (g) B : Bobot botol timbang dan Quetiapin Fumarat sebelum pemanasan (g) Weight of weighing bottle and Quetiapine Fumarate before heating (g) C : Bobot botol timbang dan Quetiapin Fumarat setelah pemanasan (g) Weight of weighing bottle and Quetiapine Fumarate after heating (g) 14. Lakukan kembali prosedur poin 9 - 14 dengan menggunakan waktu pemanasan selama 1 jam. Repeat steps 9 - 14, using a 1-hour preheating time. 15. Perbedaan antara dua kali penimbangan berturut-turut tidak lebih dari 0.5 mg. 7.1.2.3. Pembuatan Larutan Dapar pH 6.5 Preparation of pH 6.5 Buffer Solution 1. Timbang saksama 2.5 g Amonium Fosfat Dibasa ((NH₄)₂HPO₄), masukkan ke dalam gelas piala 1000 mL. Weigh accurately 2.5 g of Dibasic Ammonium Phosphate ((NH₄)₂HPO₄) and place it in a 1000 mL beaker glass. 2. Tambahkan 500 mL air murni, aduk sampai larut. Add 500 mL of purified water and stir until dissolved.	

 PT MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 12 dari 28 Pages : 12 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. :- Supersedes Number
	3. Tambahkan air murni sampai 1000 mL, aduk sampai homogen. Add distilled water to a total volume of 1000 mL, and stir until homogeneous. 4. Atur pH larutan hingga 6.5 ± 0.05 dengan menggunakan Asam Fosfat (H₃PO₄). Adjust the pH of the solution to 6.5 ± 0.05 using Phosphoric Acid (H₃PO₄). 5. Saring menggunakan vacum melalui kertas saring membran nilon 0.22 µm. Filter using a vacuum through 0.22 µm nylon membran filter. 6. Awaudarkan larutan menggunakan sonikator selama ± 10 menit. Agitate the solution using a sonicator for approximately 10 minutes. 7.1.2.4. Pembuatan Larutan Kesesuaian Sistem Quetiapin (1 mg/mL) Preparation of Quetiapine System Suitability Solution (1 mg/mL) 1. Timbang saksama 5 mg RS Kesesuaian Sistem Quetiapin, masukkan ke dalam labu ukur 5 mL. Weigh accurately 5 mg of Quetiapine System Suitability RS and place it in a 5 mL volumetric flask. 2. Tambahkan 2.5 mL pelarut, sonikasikan ± 10 menit. Add 2.5 mL of solvent, sonicate ± 10 minutes. 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to the volume, shake until homogeneous. 4. Saring larutan menggunakan syringe filter 0.45 µm PTFE. Filter the solution using PTFE 0.45 µm syringe filter. 5. Masukkan ke dalam vial KCKT. Put into HPLC vial. 7.1.2.5. Pembuatan Larutan Induk Standar (0.16 mg/mL) Preparation of Standard Stock Solution (0.16 mg/mL) 1. Timbang saksama 16 mg WS Quetiapin Fumarat, masukkan ke dalam labu ukur 100 mL. Weigh accurately 16 mg of Quetiapine Fumarate WS and place it in a 100 mL volumetric flask. 2. Tambahkan 50 mL pelarut, sonikasikan ± 10 menit. Add 50 mL of solvent, sonicate ± 10 minutes. 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to the volume, shake until homogeneous.	

 PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 13 dari 28 13 of 28 Pages No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number
	7.1.2.6. Pembuatan Larutan Standar (0.08 mg/mL) <i>Preparation of Standard Solution (0.08 mg/mL)</i> 1. Pipet 5 mL larutan induk standar, masukkan ke dalam labu ukur 10 mL. <i>Pipette 5 mL of the standard stock solution and transfer it to a 10 mL volumetric flask.</i> 2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 3. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i> 4. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i> 7.1.2.7. Pembuatan Larutan Induk Sampel (0.16 mg/mL) <i>Preparation of Sample Stock Solution (0.16 mg/mL)</i> 1. Timbang saksama 16 mg Quetiapin Fumarat, masukkan ke dalam labu ukur 100 mL. <i>Weigh accurately 16 mg of Quetiapine Fumarate and place it in a 100 mL volumetric flask.</i> 2. Tambahkan 50 mL pelarut, sonikasikan ± 10 menit. <i>Add 50 mL of solvent, sonicate ± 10 minutes.</i> 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 7.1.2.8. Pembuatan Larutan Sampel (0.08 mg/mL) <i>Preparation of Sample Solution (0.08 mg/mL)</i> 1. Pipet 5 mL larutan induk sampel, masukkan ke dalam labu ukur 10 mL. <i>Pipette 5 mL of the sample stock solution and transfer it to a 10 mL volumetric flask.</i> 2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 3. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i> 4. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i>	

 PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 14 dari 28 14 of 28 Pages No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number															
	7.1.2.9. Prosedur <i>Procedure</i> Suntikkan secara terpisah sejumlah volume yang sama pelarut, larutan kesesuaian sistem, larutan standar, dan larutan sampel ke dalam sistem kromatografi, rekam kromatogram, dan ukur respons puncak utama dengan urutan sebagai berikut. <i>Inject equal volumes of solvent, system suitability solution, standard solution, and sample solution separately into the chromatography system, record the chromatogram, and measure the main peak response in the following order.</i> Tabel 7.1. Urutan Injeksi <i>Tabel 7.1. Injection Sequence</i> <table border="1" data-bbox="1444 718 2139 1021"> <thead> <tr> <th>No.</th><th>Jenis Larutan <i>Type of Solutions</i></th><th>Jumlah Injeksi <i>Number of Injections</i></th></tr> </thead> <tbody> <tr> <td>1.</td><td>Pelarut <i>Solvent</i></td><td>1x</td></tr> <tr> <td>2.</td><td>Larutan kesesuaian sistem <i>System suitability solution</i></td><td>2x</td></tr> <tr> <td>3.</td><td>Larutan standar <i>Standard solution</i></td><td>6x</td></tr> <tr> <td>4.</td><td>Larutan sampel <i>Sample solution</i></td><td>6x</td></tr> </tbody> </table> 7.1.3. Perhitungan <i>Calculation</i> Hitung jumlah dalam % Quetiapin Fumarat dalam larutan sampel menggunakan rumus berikut. <i>Calculate % of Quetiapine Fumarate in the sample solution using the following formula.</i> $\text{Quetiapine Fumarate (as is, \%)} = \frac{\text{Rspl} \times \text{Wstd} \times \text{FPspl}}{\text{Rstd} \times \text{Wspl} \times \text{FPstd}} \times F$ $\text{Quetiapine Fumarate (dry basis, \%)} = \frac{\text{As Is}}{(100 - \text{LOD})} \times 100$ Keterangan: <i>Descriptions</i> Rspl : Respons puncak Quetiapin Fumarat dalam larutan sampel <i>Peak response of Quetiapine Fumarate in sample solution</i> Rstd : Respons puncak Quetiapin Fumarat dalam larutan standar <i>Peak response of Quetiapine Fumarate in standard solution</i>	No.	Jenis Larutan <i>Type of Solutions</i>	Jumlah Injeksi <i>Number of Injections</i>	1.	Pelarut <i>Solvent</i>	1x	2.	Larutan kesesuaian sistem <i>System suitability solution</i>	2x	3.	Larutan standar <i>Standard solution</i>	6x	4.	Larutan sampel <i>Sample solution</i>	6x	
No.	Jenis Larutan <i>Type of Solutions</i>	Jumlah Injeksi <i>Number of Injections</i>															
1.	Pelarut <i>Solvent</i>	1x															
2.	Larutan kesesuaian sistem <i>System suitability solution</i>	2x															
3.	Larutan standar <i>Standard solution</i>	6x															
4.	Larutan sampel <i>Sample solution</i>	6x															

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 15 dari 28 Pages : 15 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number
	Wspl : Bobot Quetiapin Fumarat yang ditimbang dalam larutan sampel (mg) <i>Weight of Quetiapine Fumarate weighed in the sample solution (mg)</i> Wstd : Bobot WS Quetiapin Fumarat yang ditimbang dalam larutan standar (mg) <i>Weight of Quetiapine Fumarate WS weighed in standard solution (mg)</i> FPspl : Faktor pengenceran Quetiapin Fumarat dalam larutan sampel (200) <i>Quetiapine Fumarate dilution factor in sample solution (200)</i> FPstd : Faktor pengenceran WS Quetiapin Fumarat dalam larutan standar (200) <i>Quetiapine Fumarate WS dilution factor in standard solution (200)</i> F : Kadar WS Quetiapin Fumarat sebagai as is yang digunakan (%) <i>Concentration of Quetiapine Fumarate WS as used (%)</i> As Is : Kadar Quetiapin Fumarat dalam as is (%) <i>Quetiapine Fumarate Content as is (%)</i> LOD : Hasil susut pengeringan Quetiapin Fumarat (%) <i>Loss on Drying of Quetiapine Fumarate (%)</i> 7.2. Cemaran Organik Organic Impurities 7.2.1. Alat dan Bahan <i>Tools and Materials</i> 7.2.1.1. Alat <i>Tools</i> 1. Timbangan merek Shimadzu Type AP 224 X. <i>Scales brand Shimadzu Type AP 224 X.</i> 2. KCKT merek Waters Alliance Type e2695. <i>HPLC brand Waters Alliance Tipe e2695.</i> 3. Kolom Waters Xterra RP-8 150 x 4.6 mm, 3.5 µm (L7) Cat No 186000443. <i>Waters Xterra RP-8 Column, 150 x 4.6 mm, 3.5 µm (L7), Cat. No. 186000443.</i> 4. pH meter. <i>pH meter.</i> 5. Sonikator. <i>Sonicator.</i> 6. Vacuum. <i>Vacuum.</i> 7. Gelas piala 1000 mL. <i>1000 mL beaker glass.</i>	

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 16 dari 28 Pages : 16 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : Supersedes Number
	8. Gelas ukur 500 mL. <i>500 mL measuring cylinder.</i> 9. Labu ukur 5 mL. <i>5 mL volumetric flask.</i> 10. Labu ukur 10 mL. <i>10 mL volumetric flask.</i> 11. Labu ukur 20 mL. <i>20 mL volumetric flask.</i> 12. Labu ukur 100 mL. <i>100 mL volumetric flask.</i> 13. Mikropipet. <i>Micropipette.</i> 14. Pipet volume 2 mL. <i>2 mL volumetric pipette.</i> 15. Batang pengaduk. <i>Stirring rod.</i> 16. Kertas perkamen. <i>Parchment paper.</i> 17. Spatula. <i>Spatula.</i> 18. Kertas saring membran 0.22 µm. <i>0.22 µm nylon membrane filter.</i> 19. Syringe filter 0.45 µm PTFE <i>PTFE 0.45 µm syringe filter.</i> 20. Vial KCKT. <i>HPLC vials.</i> 7.2.1.2. Bahan <i>Materials</i> 1. WS Quetiapin Fumarat <i>Quetiapine Fumarate WS</i> 2. RS Kesesuaian Sistem Quetiapin ex USP Cat No. 1592715. <i>Quetiapine System Suitability RS Cat No. 1592715.</i> 3. RS Senyawa Sejenis B Quetiapin ex Pharmaffiliates Cat No. PA 17 02020. <i>RS Quetiapine Related Compound B ex Pharmaffiliates Cat No. PA 17 02020.</i>	

**PROTOKOL TRANSFER METODE ANALISIS
PENETAPAN KADAR DAN CEMARAN ORGANIK
BAHAN BAKU QUETIAPIN FUMARAT
SECARA KCKT
ANALYTICAL METHOD TRANSFER PROTOCOL OF
ASSAY AND ORGANIC IMPURITIES OF
QUETIAPINE FUMARATE RAW MATERIAL
BY HPLC**

Halaman : 17 dari 28
Pages : 17 of 28
No. Dokumen : RD.02-PTB/135.00
Document No.
Tanggal Dokumen Disetujui :
Document Approval Date
Menggantikan No. :
Supersedes Number

4. **RS Senyawa Sejenis G Quetiapin ex Pharmaffiliates Cat No. PA 17 02070.**
RS Quetiapine Related Compound G ex Pharmaffiliates Cat No. PA 17 02070.
5. Amonium Asetat ($\text{NH}_4\text{C}_2\text{H}_3\text{O}_2$) ex Smartlab Cat No. A-2001.
Ammonium Acetate ($\text{NH}_4\text{C}_2\text{H}_3\text{O}_2$) ex Smartlab Cat No. A-2001.
6. Amonium Solution (NH_4OH) 25% ex Smartlab Cat No. A1011.
25% Amonium Solution (NH_4OH) ex Smartlab Cat. No. A1011.
7. Asetonitril (CH_3CN) ex Fisher Cat No. A998-4.
Acetonitrile (CH_3CN) ex Fisher Cat No. A998-4.
8. Air murni.
Purified water.

7.2.2. Prosedur untuk Kadar
Procedure for Assay

7.2.2.1. Kondisi Pengerjaan KCKT
HPLC Working Condition

1. Kolom : **Kolom Waters Xterra RP-8 150 x 4.6 mm, 3.5 μm (L7)**
Column : Waters Xterra RP-8 Column, 150 x 4.6 mm, 3.5 μm (L7)
2. Detektor : 250 nm
Detector : 250 nm
3. Suhu kolom : 45°C
Column temperature : 45°C
4. Laju Alir : 1.5 mL/menit
Flow Rate : 1.5 mL/minute
5. Volume penyuntikan : 20 μL
Injection volume : 20 μL
6. Fase gerak : Larutan A : Larutan B yang diprogram secara gradien
Mobile phase : Solution A : Solution B programmed as a gradient
 - a. Larutan A : Asetonitril : larutan Dapar (25 : 75)
Solution A : Acetonitril : Buffer solution (25 : 75)
 - b. Larutan B : Asetonitril
Solution B : Acetonitrile

**PROTOKOL TRANSFER METODE ANALISIS
PENETAPAN KADAR DAN CEMARAN ORGANIK
BAHAN BAKU QUETIAPIN FUMARAT
SECARA KCKT
ANALYTICAL METHOD TRANSFER PROTOCOL OF
ASSAY AND ORGANIC IMPURITIES OF
QUETIAPINE FUMARATE RAW MATERIAL
BY HPLC**

Halaman : 18 dari 28
Pages : 18 of 28
No. Dokumen : RD.02-PTB/135.00
Document No.
Tanggal Dokumen Disetujui :
Document Approval Date
Menggantikan No. :
Supersedes Number

Time (Minute)	Solution A (%)	Solution B (%)
0	100	0
25	100	0
60	29.3	70.7
60.1	100	0
68	100	0

6. Pelarut : Larutan A : Larutan B (86 : 14)
Solvent : Solution A : Solution B (86 : 14)

7. Waktu retensi
Retention time

- a. Senyawa Sejenis G Quetiapin : 14.5 menit $\pm$ 3 menit
Quetiapine Related Compound G : 14.5 minutes $\pm$ 3 minutes
- b. Senyawa Sejenis B Quetiapin : 17.5 menit $\pm$ 4 menit
Quetiapine Related Compound B : 17.5 minutes $\pm$ 4 minutes
- c. Quetiapin Desetoksi : 21.1 menit $\pm$ 4 menit
Quetiapine Desethoxy : 21.1 minutes $\pm$ 4 minutes
- d. Quetiapin Fumarat : 25.3 menit $\pm$ 5 menit
Quetiapine Fumarate : 25.3 minutes $\pm$ 5 minutes

- Catatan : 1. Gunakan labu ukur berwarna gelap/amber.
Note : Use a dark/amber volumetric flask.
2. Kondisi preparasi terlindung dari cahaya.
The preparation is protected from light.

7.2.2.2. Pembuatan Larutan Dapar
Preparation of Buffer Solution

1. Timbang saksama 3.1 g Amonium Asetat ($\text{NH}_4\text{C}_2\text{H}_3\text{O}_2$), masukkan ke dalam gelas piala 1000 mL.
Weigh accurately 3.1 g of Ammonium Acetate ($\text{NH}_4\text{C}_2\text{H}_3\text{O}_2$) and place it in a 1000 mL beaker glass.
2. Tambahkan 500 mL air mumi, aduk sampai larut.
Add 500 mL purified water, stir until dissolved.
3. Tambahkan air murni hingga 1000 mL, aduk sampai homogen.
Add purified water up to 1000 mL, stir until homogeneous.
4. Tambahkan 2 mL Amonium Solution (NH_4OH) 25%, aduk sampai homogen.
Add 2 mL of 25% Ammonium Hydroxide (NH_4OH) solution and stir until homogeneous.

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 19 dari 28 Pages : 19 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. :- Supersedes Number
	5. Nilai pH yang dihasilkan tidak kurang dari 9.2. <i>The pH of the resulting solution is not less than 9.2.</i> 6. Saring menggunakan vacum melalui kertas saring membran nilon 0.22 µm. <i>Filter using a vacuum through 0.22 µm nylon membran filter.</i> 7. Awaudarakan larutan menggunakan sonikator selama ± 10 menit. <i>Agitate the solution using a sonicator for approximately 10 minutes.</i> 7.2.2.3. Pembuatan Larutan Induk Standar (0.1 mg/mL) <i>Preparation of Standard Stock Solution (0.1 mg/mL)</i> 1. Timbang saksama 2 mg WS Quetiapin Fumarat, masukkan ke dalam labu ukur 20 mL. <i>Weigh accurately 2 mg of Quetiapine Fumarate WS and place it in a 20 mL volumetric flask.</i> 2. Tambahkan 10 mL pelarut, sonikasikan ± 10 menit. <i>Add 10 mL of solvent, sonicate ± 10 minutes.</i> 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 7.2.2.4. Pembuatan Larutan Induk Senyawa Sejenis B Quetiapin (0.1 mg/mL) <i>Preparation of Quetiapine Related Compound B Stock Solution (0.1 mg/mL)</i> 1. Timbang saksama 2 mg RS Senyawa Sejenis B Quetiapin, masukkan ke dalam labu ukur 20 mL. <i>Weigh accurately 2 mg of Quetiapine Related Compound B RS and place it in a 20 mL volumetric flask.</i> 2. Tambahkan 10 mL pelarut, sonikasikan ± 10 menit. <i>Add 10 mL of solvent, sonicate ± 10 minutes.</i> 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 7.2.2.5. Pembuatan Larutan Induk Senyawa Sejenis G Quetiapin (0.02 mg/mL) <i>Preparation of Quetiapine Related Compound G Stock Solution (0.02 mg/mL)</i> 1. Timbang saksama 2 mg RS Senyawa Sejenis G Quetiapin, masukkan ke dalam labu ukur 100 mL. <i>Weigh accurately 2 mg of Quetiapine Related Compound G RS and place it in a 100 mL volumetric flask.</i> 2. Tambahkan 10 mL pelarut, sonikasikan ± 40 menit. <i>Add 10 mL of solvent, sonicate ± 40 minutes.</i> 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i>	

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 20 dari 28 Pages : 20 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. :- Supersedes Number
	7.2.2.6. Pembuatan Larutan Identifikasi Puncak (Quetiapin Fumarat 0.001 mg/mL, Senyawa Sejenis B Quetiapine 0.01 mg/mL, Senyawa Sejenis G Quetiapin 0.002 mg/mL) <i>Preparation of Peak Identification Solution (Quetiapine Fumarate 0.001 mg/mL, Quetiapine Related Compound B 0.01 mg/mL, Quetiapine Related Compound G 0.002 mg/mL)</i> 1. Pipet masing-masing 0.1 mL larutan stok standar, 1 mL larutan induk Senyawa Sejenis B Quetiapin, dan 1 mL larutan induk Senyawa Sejenis G Quetiapin, masukkan ke dalam labu ukur 10 mL. <i>Pipette 0.1 mL of the standard stock solution, 1 mL of the Quetiapine Related Compound B stock solution, and 1 mL of the Quetiapine Related Compound G stock solution, and transfer them to a 10 mL volumetric flask.</i> 2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 3. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i> 4. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i> Catatan: Note Senyawa Sejenis B Quetiapine akan menjadi puncak terbesar pada kromatogram larutan identifikasi puncak. <i>Quetiapine Related Compound B will be the largest peak in the peak identification solution chromatogram.</i> 7.2.2.7. Pembuatan Larutan Kesesuaian Sistem (1 mg/mL) <i>Preparation of System Suitability Solution (1 mg/mL)</i> 1. Timbang saksama 5 mg RS Kesesuaian Sistem Quetiapin, masukkan ke dalam labu ukur 5 mL. <i>Weigh accurately 5 mg of Quetiapine System Suitability RS and place it in a 5 mL volumetric flask.</i> 2. Tambahkan 2.5 mL pelarut, sonikasikan ± 10 menit. <i>Add 2.5 mL of solvent, sonicate ± 10 minutes.</i> 3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 4. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i>	

 PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 21 dari 28 Pages : 21 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : - Supersedes Number
	5. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i> 7.2.2.8. Pembuatan Larutan Standar (0.001 mg/mL) <i>Preparation of Standard Solution (0.001 mg/mL)</i> 1. Pipet 0.1 mL larutan induk standar, masukkan ke dalam labu ukur 10 mL. <i>Pipette 0.1 mL of the standard stock solution and transfer it to a 10 mL volumetric flask.</i> 2. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 3. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i> 4. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i> 7.2.2.9. Pembuatan Larutan Sampel (1.0 mg/mL) <i>Preparation of Sample Solution (1.0 mg/mL)</i> 1. Timbang saksama 50 mg Quetiapine Fumarat, masukkan ke dalam labu ukur 50 mL. <i>Weigh accurately 50 mg of Quetiapine Fumarate and place it in a 50 mL volumetric flask.</i> 2. Tambahkan 25 mL larutan A, sonikasikan ± 10 menit. <i>Add 25 mL of solution A, sonicate ± 10 minutes.</i> 3. Tambahkan larutan A sampai tanda batas, kocok sampai homogen. <i>Add solution A up to the volume, shake until homogeneous.</i> 4. Saring larutan menggunakan syringe filter 0.45 µm PTFE. <i>Filter the solution using PTFE 0.45 µm syringe filter.</i> 5. Masukkan ke dalam vial KCKT. <i>Put into HPLC vial.</i> 7.2.2.10. Prosedur <i>Procedure</i>	
	Suntikkan secara terpisah sejumlah volume yang sama pelarut, larutan induk Senyawa Sejenis G Quetiapine, larutan induk Senyawa Sejenis B Quetiapine, larutan identifikasi puncak, larutan kesesuaian sistem, larutan standar, dan larutan sampel ke dalam sistem kromatografi, rekam kromatogram, dan ukur respons puncak utama dengan urutan sebagai berikut.	

 PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISIS PENETAPAN KADAR DAN CEMARAN ORGANIK BAHAN BAKU QUETIAPIN FUMARAT SECARA KCKT ANALYTICAL METHOD TRANSFER PROTOCOL OF ASSAY AND ORGANIC IMPURITIES OF QUETIAPINE FUMARATE RAW MATERIAL BY HPLC	Halaman : 22 dari 28 Pages : 22 of 28 No. Dokumen : RD.02-PTB/135.00 Document No. Tanggal Dokumen Disetujui : Document Approval Date Menggantikan No. : - Supersedes Number																								
	<i>Inject equal volumes of solvent, Quetiapine Related Compound G stock solution, Quetiapine Related Compound B stock solution, peak identification solution, system suitability solution, standard solution, and sample solution separately into the chromatography system, record the chromatogram, and measure the main peak response in the following order.</i> Tabel 7.2. <u>Urutan Injeksi</u> Tabel 7.2. Injection Sequence <table border="1"> <thead> <tr> <th>No. No.</th><th>Jenis Larutan Type of Solutions</th><th>Jumlah Injeksi Number of Injections</th></tr> </thead> <tbody> <tr> <td>1.</td><td>Pelarut Solvent</td><td>1x</td></tr> <tr> <td>2.</td><td>Larutan induk Senyawa Sejenis G Quetiapine Quetiapine Related Compound G stock solution</td><td>1x</td></tr> <tr> <td>3.</td><td>Larutan induk Senyawa Sejenis B Quetiapine Quetiapine Related Compound B stock solution</td><td>1x</td></tr> <tr> <td>4.</td><td>Larutan identifikasi puncak Peak identification solution</td><td>1x</td></tr> <tr> <td>5.</td><td>Larutan kesesuaian sistem System suitability solution</td><td>2x</td></tr> <tr> <td>6.</td><td>Larutan standar Standard solution</td><td>6x</td></tr> <tr> <td>7.</td><td>Larutan sampel Sample solution</td><td>6x</td></tr> </tbody> </table>	No. No.	Jenis Larutan Type of Solutions	Jumlah Injeksi Number of Injections	1.	Pelarut Solvent	1x	2.	Larutan induk Senyawa Sejenis G Quetiapine Quetiapine Related Compound G stock solution	1x	3.	Larutan induk Senyawa Sejenis B Quetiapine Quetiapine Related Compound B stock solution	1x	4.	Larutan identifikasi puncak Peak identification solution	1x	5.	Larutan kesesuaian sistem System suitability solution	2x	6.	Larutan standar Standard solution	6x	7.	Larutan sampel Sample solution	6x	
No. No.	Jenis Larutan Type of Solutions	Jumlah Injeksi Number of Injections																								
1.	Pelarut Solvent	1x																								
2.	Larutan induk Senyawa Sejenis G Quetiapine Quetiapine Related Compound G stock solution	1x																								
3.	Larutan induk Senyawa Sejenis B Quetiapine Quetiapine Related Compound B stock solution	1x																								
4.	Larutan identifikasi puncak Peak identification solution	1x																								
5.	Larutan kesesuaian sistem System suitability solution	2x																								
6.	Larutan standar Standard solution	6x																								
7.	Larutan sampel Sample solution	6x																								
	7.2.3. Perhitungan Calculation 7.2.3.1. Masing-masing Cemaran Individu Each Individual Impurity Hitung jumlah dalam % masing-masing cemaran individu Quetiapine Fumarat dalam larutan sampel menggunakan rumus berikut. Calculate the percentage of each individual impurity in the Quetiapine Fumarate sample solution using the following formula. $\text{Any Individual Impurity} = \frac{Rspl \times Wstd \times FPspl \times 1}{Rstd \times Wspl \times FPstd \times F} \times 100$																									

Rencana Kebutuhan RS Quetiapin (USP)

No	Nama Produk	Keperluan	Pembakuan (kali) (a)	Sekali Penggunaan (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Quetiapin	Pembakuan <i>Working Standar</i>	2	16	32
Total (mg)					32

Kesimpulan : Dibutuhkan sebanyak 32 mg RS Quetiapin, Quantity 1 Vial @ 200 mg sehingga dibutuhkan **1 vial**



Store

Menu

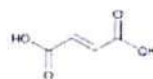
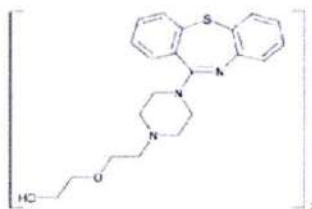
Search by product name or number, CAS#, molecular formula, or lot number



Sign in

Quick order

Home > Products > Small Molecules > Associated Drug Substance > Quetiapine Fumarate



Catalog no. 1592704 CAS RN[®] 111974-72-2



Quetiapine Fumarate
200 mg

\$283.00

- 1 +

Add to cart - \$283.00



In Stock

Ready to ship

Shipping Information

Handwritten signature and date: 01/26/20

Images are for purely illustrative purposes and may not reflect actual products

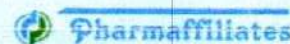
Current Lot Number	R065W0
Molecular formula	(C ₂₁ H ₂₅ N ₃ O ₇ S) ₂ · C ₄ H ₄ O ₄
Harmonized System (HS) Code	293499
Container Type	VIAL
Country of origin	United Kingdom

Rencana Kebutuhan Quetiapin Related Compound B (Pharmaffiliates)

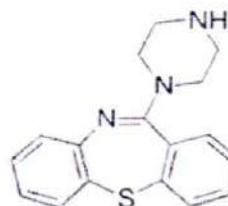
No	Nama Produk	Keperluan	Pengujian BB (kali) (a)	Sekali Penggunaan (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Quetiapin	Cemaran Organik	2	2	4
TOTAL					4

Kesimpulan : Dibutuhkan sebanyak 4 mg RS Quetiapin Related Compound B (Pharmaffiliates), Qty 1 Vial @ 25 mg sehingga dibutuhkan 1 vial

Certificate of Analysis



Product Name	Quetiapine Related Compound B
Lot No.	PA/QUE/01202
Product Code	PA 17 02020
CAS No.	111974-74-4
Release Date	25 Mar 2025
Retest Date	24 Mar 2027
Molecular Weight	295.4+72.92
Molecular Formula	C ₁₇ H ₁₈ Cl ₂ N ₃ S
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	Quetiapine DBTP Metabolite; Dibenzo[b,f][1,4]thiazepine-11-yl-piperazine dihydrochloride; Quetiapine Related Compound B (USP - Base); 11-(piperazin-1-yl)dibenzo[b,f][1,4]thiazepine Dihydrochloride;



• 2HCl

ANALYTICAL INFORMATION

S. No.	Tests	Result	Specifications
1.	Description	Off white crystalline powder	White to off white crystalline powder
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	Chromatographic Purity (% by HPLC) *	97.1	NLT 90.0

Summary Product is characterized by using IR, NMR, MS, HPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

Quality concern, if any: Inform within three months of Invoice Date.

*Retest Value

Date of Issue 28 Mar 2025

Vial No. : 295
Version : 05



Authorized Signatory

(Lakhwinder Singh)
Lot Certifier
SR

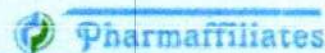
Signature
01/26/26

Rencana Kebutuhan Quetiapin Related Compound G (Pharmaffiliates)

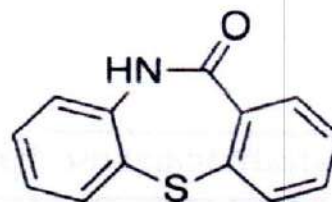
No	Nama Produk	Keperluan	Pengujian BB (kali) (a)	Sekali Penggunaan (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Quetiapin	Cemaran Organik	2	2	4
TOTAL					4

Kesimpulan : Dibutuhkan sebanyak 4 mg RS Quetiapin Related Compound G (Pharmaffiliates), Qty 1 Vial @ 25 mg sehingga dibutuhkan 1 vial

Certificate of Analysis



Product Name	Quetiapine Related Compound G
Lot No.	PA/QUE/01207
Product Code	PA 17 02070
CAS No.	3159-07-7
Release Date	07 Mar 2025
Retest Date	06 Mar 2027
Molecular Weight	227.28
Molecular Formula	C ₁₃ H ₉ NOS
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	Quetiapine DBTO Metabolite; 10,11-Dihydro-11-oxodibenz[b,f][1,4]thiazepine; 10,11-Dihydrodibenzo[b,f][1,4]thiazepin-11-one; Dibenzo[b,f][1,4]thiazepin-11(10H)-one; Quetiapine Related Compound G (USP);



ANALYTICAL INFORMATION			
S. No.	Tests	Result	Specifications
1.	Description	Off white powder	White to off white powder
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	Chromatographic Purity (% by UPLC)*	99.9	NLT 90.0

Summary Product is characterized by using IR, NMR, MS, UPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

Quality concern, if any: Inform within three months of Invoice Date.

*Retest value

Date of Issue 14 May 2025

Vial No. : 1703
Version : 05



Authorized Signatory

(A. Bhardwaj)
Lot Certifier
SR

(Signature)
01/06/26

Rencana Kebutuhan Quetiapin System Suitability (USP)

No	Nama Produk	Keperluan	Pengujian BB (kali) (a)	Sekali Penggunaan (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Quetiapin	Kadar	2	5	10
2	Quetiapin	Cemaran Organik	2	5	10
TOTAL					20

Kesimpulan : Dibutuhkan sebanyak 20 mg RS Quetiapin System Suitability (USP), Qty 1 Vial @ 25 mg sehingga dibutuhkan **1 vial**

Home / Small Molecules / System Suitability / Quetiapine System Suitability (25 mg) (Mixture contains Quetiapine Fumarate and about 1% each of Quetiapine Related Compound B, Quetiapine Related Compound G and Quetiapine Desethoxy)

Ready to ship

\$1,000.00

Frequently Purchased



Quetiapine System Suitability (25 mg) (Mixture contains Quetiapine Fumarate and about 1% each of Quetiapine Related Compound B, Quetiapine Related Compound G and Quetiapine Desethoxy)

Catalog No:
1592715

CAS RN®:
-

1

Add to cart

Molecular
Formula:
**(C₂₁H₂₅N₃O₂
S)₂.C₄H₄O₄**

Product Type:
**Reference
Standard**

Add to Favorites

Shipping Information

Related Products

tert-Butylmethyl ether (1.2 mL/ampule; 3 ampules)

Catalog No:
1083303

CAS RN®:
1634-04-4

Molecular Formula:
C₅-H₁₂-O

Product Type:
Reference Stand:

\$297.00

1

Add to cart

THIS ITEM HAS BEEN IDENTIFIED AS A POTENTIALLY DANGEROUS GOOD. SPECIAL SHIPPING METHODS AND CHARGES MAY APPLY.

Handwritten signature and date: 01/11/24

Abiraterone Acetate (200 mg)

Catalog No:
1000818

CAS RN®:
154229-18-2