



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. Dokumen :PV/AD/BB/2025/009.1.00

Disusun Oleh :

Nama	Jabatan	Tanda Tangan
Puthut Arief Bintoro	<i>R&D Analytical Development Supervisor</i>	

Diperiksa Oleh :

Nama	Jabatan	Tanda Tangan
Iin Agreeani Sitohang	<i>R&D Analytical Development Manager</i>	



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

1. TUJUAN

Untuk melakukan penyesuaian spesifikasi dan metode analisis kadar *Methisoprinol* terhadap referensi terbaru dan sesuai dengan tujuan penerapannya.

2. RUANG LINGKUP

Protokol ini ditujukan untuk validasi kadar bahan baku *Methisoprinol*.

3. REFERENSI

In house method mengacu *analytical method of manufacturer* tahun 2023 (*ABC Farmaceutici*)

4. TANGGUNG JAWAB

R&D Analytical Development Scientist bertanggung jawab melaksanakan verifikasi metode analisis sesuai dengan protokol verifikasi metode analisis, mencatat semua informasi / data dan hasil yang diperoleh dari pelaksanaan.

R&D Analytical Development Supervisor bertanggung jawab merencanakan verifikasi metode analisis, membuat protokol verifikasi, mengawasi kinerja dan memastikan kelengkapan catatan analisis.

R&D Analytical Development Manager bertanggung jawab mengkaji dan menyetujui protokol sebelum dilaksanakan verifikasi metode analisis, menilai data dan memberikan persetujuan dalam laporan verifikasi metode analisis.

5. PARAMETER VALIDASI

Akan dilakukan validasi terhadap analisis kadar *Methisoprinol* mencakup parameter sebagai berikut:

5.1. Uji Kesesuaian Sistem (UKS)

5.2. Spesifisitas

5.3. Linieritas

5.4. Akurasi

5.5. Presisi

5.5.1. Ripitabilitas

5.5.2. Presisi Antara



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

5.6. *Robustness*

5.7. *Range*

6. *REAGEN DAN MATERIAL*

Reagen

No	Nama Reagen	Grade
1	Potassium dihydrogen phosphate	Analytical
2	Ortho phosphoric acid 80%	Analytical
3	Methanol	HPLC
4	Purified water	HPLC

Material

1. *Methisoprinol RS*
2. *Sampel Methisoprinol*

7. *METODE*

7.1. *Sistem kromatografi*

Alat	: HPLC Agilent Infinity II			
Kolom	: Purospher L1; 4,6 mm x 15 cm (5µm)			
Fase gerak	Waktu (menit)	Larutan A (%)	Larutan B (%)	Curve
	5	95	5	0
	10	90	10	1
	25	40	60	1
	32	40	60	0
	35	95	5	1
	40	95	5	0
Pelarut	: Purified water, methanol			
Suhu kolom	: 25 °C			
Suhu auto sampler	: 20 °C			



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

Detektor	: 254 nm
Lajualir	: 1 mL/menit
Volume injek	: 20 μ L
Run time	: 40 menit

7.2. Pembuatan Larutan (Dibuat sesuai dengan kebutuhan)

Larutan A

1. Timbang 2.65 g *potassium dihydrogen phosphate* masukkan ke dalam *beaker glass* 1000 mL.
2. Larutkan dan encerkan dengan 1000 mL air, aduk hingga homogen.
3. Atur pH larutan dengan penambahan *ortho phosphoric acid 80%* hingga dicapai pH 3.5. Saring dan *degass*.

Larutan B

Gunakan *Methanol P*. Saring dan *degass*.

8. PROSEDUR

Larutan standar dan larutan sampel *Methisoprinol* mengandung 2 zat aktif yaitu *Inosine* dan *4-Acetamido benzoic acid salt*

8.1. Uji Kesesuaian Sistem

Larutan Identifikasi Inosine

1. Timbang **120,3 mg Inosine RS** masukkan ke dalam labu ukur 50 mL.
2. Larutkan dengan 25 mL *methanol*, kocok hingga larut.
3. **Pipet 1,0 mL larutan**, masukkan ke dalam labu ukur 20 mL
4. Tambahkan purified water hingga tanda batas kemudian kocok hingga homogen.
5. Saring larutan menggunakan membrane filter 0,45 μ m ke vial LC. ($C_{Inosine RS} = 0,120$ mg/mL).



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl: -

Larutan Standar

1. Timbang **10 mg Methisoprinol RS** masukkan ke dalam labu ukur 20 mL.
2. Larutkan dengan 10,0 mL *purified water*, kocok hingga larut.
3. Tambahkan dengan *purified water* hingga tanda batas kemudian kocok hingga homogen.
4. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol RS}} = 0,5 \text{ mg/mL}$).

Catatan :

- Preparasi **Larutan Identifikasi Inosine** dilakukan untuk mengidentifikasi dengan tepat retention time dari *Inosine* dan *4-acetamido benzoic acid salt* dalam campuran *Methisoprinol*.
- Pembuatan **Larutan Standar** : jumlah penimbangan menyesuaikan dengan *minimum weight* dari alat timbang yang tersedia. Buat larutan hingga didapat konsentrasi akhir yang sama.

Pengukuran

Komponen	Replikasi Preparasi	Replikasi Injeksi
Pelarut	1	2
Larutan Identifikasi	1	3
Larutan standar	1	5

Kriteria Penerimaan

Komponen	Parameter	Kriteria penerimaan
Larutan Standar	% RSD <i>Inosine</i> dan <i>4-acetamido benzoic acid salt</i>	$\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan <i>4-acetamido benzoic acid salt</i>	0,8 – 1,5



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

8.2. Spesifisitas

Larutan Fase Gerak

Suntikkan 20 µL larutan **Fase gerak** yang sudah disaring dengan *membrane filter* 0,45 µm ke dalam alat HPLC yang telah dikondisikan.

Larutan Pelarut

Suntikkan 20µL larutan **Pelarut** yang sudah disaring dengan *membrane filter* 0,45 µm ke dalam alat HPLC yang telah dikondisikan.

Kriteria Penerimaan

Parameter	Kriteria Penerimaan
Interferensi fase gerak	Tidak ada interferensi dari fase gerak
Interferensi pelarut	Tidak ada interferensi dari pelarut
<i>Retention Time</i>	<i>Retention time peak Methisoprinol</i> pada larutan sampel sesuai dengan <i>peak Methisoprinol</i> pada larutan standar

8.3. Linieritas

Lima rentang linieritas yang digunakan pada parameter lainnya yaitu 50%, 75%, 100%, 125% dan 150%

Larutan Induk *Methisoprinol RS*

1. Timbang **25 mg *Methisoprinol RS*** masukkan ke dalam labu ukur 10 mL.
2. Larutkan dengan 5,0 mL *purified water*, kocok hingga larut.
3. Tambahkan dengan *purified water* hingga tanda batas kemudian kocok hingga homogen. ($C_{\text{Methisoprinol RS}} = 2,5 \text{ mg/mL}$)



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

Linieritas 50%

1. Pipet 0,5 mL Larutan Induk *Methisoprinol RS* masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan. ($C_{\text{Methisoprinol RS}} = 0,25 \text{ mg/mL}$)

Linieritas 75%

1. Pipet 0,75 mL Larutan Induk *Methisoprinol RS* masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol RS}} = 0,375 \text{ mg/mL}$)

Linieritas 100%

1. Pipet 1,0 mL Larutan Induk *Methisoprinol RS* masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol RS}} = 0,5 \text{ mg/mL}$)

Linieritas 125%

1. Pipet 1,25 mL Larutan Induk *Methisoprinol RS* masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol RS}} = 0,625 \text{ mg/mL}$)

Linieritas 150%

1. Pipet 1,5 mL Larutan Induk *Methisoprinol RS* masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol RS}} = 0,75 \text{ mg/mL}$)



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl: -

Injeksikan larutan dalam sistem kromatografi, sebagai berikut:

Komponen	Replikasi Preparasi	Replikasi Injeksi
Pelarut	1	1
Larutan linieritas 50%	1	3
Larutan linieritas 75%	1	3
Larutan linieritas 100%	1	3
Larutan linieritas 125%	1	3
Larutan linieritas 150%	1	3

Kriteria Penerimaan

Parameter	Kriteria penerimaan
Linieritas (R^2)	$\geq 0,990$

8.4. Akurasi

Larutan standar

Lakukan sesuai prosedur 8.1 pada Uji Kesesuaian Sistem.

Larutan Induk Sampel

1. Timbang **125 mg sampel Methisoprinol** masukkan ke dalam labu ukur 50 mL.
2. Larutkan dengan 10,0 mL *purified water*, kocok hingga larut.
3. Tambahkan dengan *purified water* hingga tanda batas kemudian kocok hingga homogen. ($C_{\text{Methisoprinol Induk}} = 2,5 \text{ mg/mL}$)

Akurasi 80%

1. Pipet **1,6 mL Larutan Induk Sampel** masukkan ke dalam labu ukur 10 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45 μm ke vial LC. ($C_{\text{Methisoprinol}} = 0,4 \text{ mg/mL}$)



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

Akurasi 100%

1. Pipet 2,0 mL Larutan Induk Sampel masukkan ke dalam labu ukur 10 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Methisoprinol} = 0,5$ mg/mL)

Akurasi 120%

1. Pipet 2,4 mL Larutan Induk Sampel masukkan ke dalam labu ukur 10 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Methisoprinol} = 0,6$ mg/mL)

Pengukuran

Injeksikan larutan dengan urutan sebagai berikut:

Komponen	Replikasi Preparasi	Replikasi Injeksi
Pelarut	1	2
Larutan standar	1	5
Larutan akurasi 80%	3	1
Larutan akurasi 100%	3	1
Larutan akurasi 120%	3	1

Perhitungan :

Hitung bobot *recovery* dari *Inosine* dan *4-acetamido benzoic acid salt*:

$$\text{Bobot Recovery} = \frac{ru}{rs} \times \frac{Du}{Ds} \times Ws$$



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

Keterangan :

ru = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan akurasi

rs = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

Du = Faktor pengenceran dari larutan akurasi

Ds = Faktor pengenceran dari larutan standar

Ws = Bobot penimbangan dari larutan standar(mg)

Hitung bobot % *recovery* dari *Inosine* dan *4-acetamido benzoic acid salt*:

$$\% \text{ Recovery} = \frac{\text{Bobot recovery}}{\text{Bobot aktual}} \times 100\%$$

Kriteria Penerimaan

Parameter	Kriteria penerimaan
Rata-rata % <i>Recovery</i> larutan akurasi	98,0 – 102,0%

8.5. Presisi

8.5.1. Ripitabilitas

Ripitabilitas dilakukan bersama dengan akurasi pada replikasi 3x. Ripitabilitas dievaluasi dari % RSD dari setiap konsentrasi.

Kriteria Penerimaan

Parameter	Kriteria penerimaan
Rata-rata %RSD	≤ 2,0%



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

8.5.2. Presisi Antara

Presisi antara dilakukan dengan analisis berbeda pada hari yang berbeda.

Larutan Standar

Lakukan sesuai prosedur 8.1 pada Uji Kesesuaian Sistem.

Larutan Sampel

1. Timbang 25 mg sampel *Methisoprinol*, masukkan ke dalam labu ukur 50 mL.
2. Larutkan dengan 50 mL *purified water*, kocok hingga larut.
3. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
4. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Methisoprinol}$ = 0,5 mg/mL)

Pengukuran

Injeksikan larutan dalam sistem kromatografi, sebagai berikut:

Komponen	Replikasi Preparasi	Replikasi Injeksi
Pelarut	1	2
Larutan Standar	1	5
Larutan Sampel	6	1

Perhitungan

Hitung % kadar *Inosine* dan *4-acetamido benzoic acid salt* dengan rumus:

$$\% \text{ Kadar} = \frac{r_u}{r_s} \times \frac{W_s}{W_u} \times \frac{P}{(100-KF)} \times \frac{D_u}{D_s} \times 100$$



PT. PHAROSINDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl: -

Keterangan :

ru = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan sampel

rs = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

Ws = Bobot penimbangan dari larutan standar (mg)

Wu = Bobot penimbangan dari larutan sampel (mg)

P = Potensi Methisoprinol RS (%)

Du = Faktor pengenceran dari larutan sampel

Ds = Faktor pengenceran dari larutan standar

KF = Kadar air sampel

Kriteria Penerimaan

Parameter	Kriteria Penerimaan
Kadar <i>Inosine</i>	95,0 - 105,0%
Kadar <i>4-acetamido benzoic acid salt</i>	95,0 - 105,0%

Pengukuran

Injeksikan larutan dalam sistem kromatografi, sebagai berikut:

Komponen	Replikasi Preparasi	Replikasi Injeksi
Pelarut	1	2
Larutan standar	1	3
Larutan sampel	6	1



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :

08 SEP 2025

Mengganti: -

Tgl : -

8.6. Range

Range validasi metode analisis ini adalah 50% - 150%

8.7. Robustness

Robustness akan dilakukan dengan parameter yaitu kestabilan larutan

Kestabilan Larutan

Ukur stabilitas dari larutan standar dan larutan sampel pada rentang waktu 0, 3, 6, 9, 12, dan 24 jam

Larutan Standar

Injeksikan larutan standar dalam sistem kromatografi, sebagai berikut:

Nama Larutan	Replikasi preparasi	Replikasi Injeksi
Larutan Standar 0 jam	1	3
Larutan Standar 3 jam	1	3
Larutan Standar 6 jam	1	3
Larutan Standar 9 jam	1	3
Larutan Standar 12 jam	1	3
Larutan Standar 24 jam	1	3

Perhitungan

Hitung % *recovery* larutan standar dari masing - masing larutan dibandingkan dengan larutan 0 jam.

$$\% Recovery Standar = \frac{rs \text{ jam ke } - (n)}{rs \text{ jam ke } - 0} \times 100\%$$

Keterangan :

rs = Respon area *peak inosine* dan *4-acetamido benzoic acid salt* dari larutan standar



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

Larutan Sampel

Injeksikan larutan sampel dalam sistem kromatografi, sebagai berikut:

Nama Larutan	Replikasi preparasi	Replikasi Injeksi
Larutan Sampel 0 jam	1	3
Larutan Sampel 3 jam	1	3
Larutan Sampel 6 jam	1	3
Larutan Sampel 9 jam	1	3
Larutan Sampel 12 jam	1	3
Larutan Sampel 24 jam	1	3

Perhitungan

Hitung % *recovery* larutan sampel dari masing – masing larutan dibandingkan dengan larutan 0 jam.

$$\% Recovery Sampel = \frac{ru \text{ jam ke } - (n)}{ru \text{ jam ke } - 0} \times 100\%$$

Keterangan :

ru = Respon area *peak inosine* dan *4-acetamido benzoic acid salt* dari larutan sampel

Kriteria Penerimaan

Parameter	Kriteria penerimaan
% <i>Recovery</i> larutan standar dan larutan sampel	98,0 – 102,0%

8.8. Dokumentasi

- Kromatogram larutan sampel dan kromatogram larutan standar terlampir dalam laporan verifikasi.
- Data penimbangan dicatat pada lembar *raw data* verifikasi metode analisis.



PT. PHAROS INDONESIA

**PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

9. REVALIDASI

Revalidasi dilakukan apabila terdapat perubahan acuan monografi, sistem kromatografi atau konsentrasi larutan. Pengujian revalidasi dapat dilakukan validasi penuh atau validasi parsial sesuai justifikasi.



PT. PHAROS INDONESIA

PROTOKOL VALIDASI METODA
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
PV/AD/BB/2025/009.1.00

Tanggal Berlaku :
08 SEP 2025

Mengganti: -
Tgl : -

10. SEJARAH PERUBAHAN

No.	No. Dokumen	Tgl. berlaku	Menggantikan		Keterangan
			Dokumen No.	Tgl. Berlaku	
1.	PV/AD/BB/2025/009.1.00	08 SEP 2025	NA	NA	Dokumen baru berdasarkan <i>In house method</i> mengacu <i>analytical method of manufacturer (ABC FarmaceuticiS pA.)</i>



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE ANALISIS KADAR
DALAM BAHAN BAKU

METHISOPRINOL

No. Dokumen : LV/AD/BB/2025/009.1.00

Disusun Oleh :

Nama	Jabatan	Tanda Tangan
Puthut Arief Bintoro	<i>R&D Analytical Development Supervisor</i>	

Diperiksa Oleh :

Nama	Jabatan	Tanda Tangan
Iin Agreeani Sitohang	<i>R&D Analytical Development Manager</i>	



PT. PHAROS INDONESIA

**LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

1. TUJUAN

Untuk melakukan penyesuaian spesifikasi dan metode analisis kadar dalam bahan baku *Methisoprinol* terhadap monografi terbaru dan sesuai dengan tujuan penerapannya.

2. RUANG LINGKUP

Validasi ini dilakukan terhadap metode analisis penetapan kadar dalam bahan baku *Methisoprinol* dengan menggunakan metode HPLC.

3. REFERENSI

In house method mengacu *analytical method of manufacturer* tahun 2023 (ABC Farmaceutici)

4. PERSONIL

R&D Analytical Development Scientist : Sri Komala dan Jelly Martha Herlin

R&D Analytical Development Supervisor : Puthut Arief Bintoro

R&D Analytical Development Manager : Iin Agreeani Sitohang

5. INFORMASI INSTRUMEN

Tabel 1. Instrumen

No.	Instrumen	Brand/Type	No. Instrumen	Tanggal Re-Kalibrasi
1	HPLC	Agilent/1260 - 600 bar	PI-AD-HPC-044	02 Agustus 2026
		Agilent/1260 - 600 bar	PI-AD-HPC-109	09 Juli 2026
2	Timbangan	Sartorius/ BCE224I-1S	PI-AD-TBG-062	04 September 2026
			PI-AD-TBG-065	10 September 2026
3	Sonikator	Daihan/LUC-420	PI-AD-UTR-056	NA
4	pH Meter	Mettler Toledo/Seven Direct SD20	PI-AD-PHM-102	30 Januari 2026
5	Ultrapure Water System	Sartorius/ Arium Comfort	PI-AD-ARC-049	NA



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

6. INFORMASI REAGEN DAN MATERIAL

Tabel 2. Reagen

No.	Reagen	Grade	Manufacturer	No. Batch/Lot	Expired Date
1.	Potassium Dihydrogen Phosphate	Analysis	Merck	AM2015173426	30 November 2028
2.	Ortho Phosphoric Acid 80%	Analysis	Merck	K53202673110	31 Agustus 2027
3.	Methanol	HPLC	Merck	I1382207448	30 November 2027
4.	Purified Water	HPLC	Fresh		

Tabel 3. Material

No.	Material	Manufacturer	Formula/ Batch No.	Manufacturing Date	Expired Date
1.	Methisoprinol	BPFI	AB0122678	Current Lot	Current Lot
2.	Inosine	TRC	2023-CPO-018	26 Januari 2023	24 Januari 2027
3.	Methisoprinol	Unibios	MTP250225	April 2025	30 April 2028

7. DEVIASI

Tidak ada deviasi dari protokol.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

8. HASIL

8.1 Uji Kesesuaian Sistem

Tabel 4. Larutan Identifikasi

No.	Konsentrasi (mg/mL)	<i>Inosine</i>		
		<i>Retention Time</i> (Menit)	Area	<i>Tailing Factor</i>
1	0,12 <i>as Inosine</i>	9,3	5439,3889	1,1
2		9,3	5436,0212	1,1
3		9,3	5437,8306	1,1
Rata-rata		9,3	5437,7469	1,1
<i>RSD (%)</i>		<i>NA</i>	0,03%	<i>NA</i>

Tabel 5. Larutan Standar

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Tailing Factor	Retention Time (Menit)	Area	Tailing Factor
1	0,5 as Methisoprinol	9,5	5523,3820	1,1	20,4	18042,1536	1,0
2		9,5	5522,1712	1,1	20,3	18081,7408	1,0
3		9,5	5521,6640	1,1	20,3	18120,5194	1,0
4		9,3	5522,8146	1,1	20,3	18082,8304	1,0
5		9,3	5519,5853	1,1	20,2	18070,9052	1,0
Rata-rata		9,4	5521,9234	1,1	20,3	18079,6299	1,0
RSD (%)		NA	0,03%	NA	NA	0,16%	NA

Keterangan :

RSD (Relative Standard Deviation)

NA (Not Applicable)



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 6. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Standar	%RSD area peak <i>Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	0,03% dan 0,16%	$\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	1,1 dan 1,0	$\leq 1,5$

Kesimpulan: Uji kesesuaian sistem memenuhi syarat.

8.2 Spesifisitas

Tabel 7. Spesifisitas Fase gerak

No.	Area Fase Gerak pada <i>Retention Time</i> (RT) <i>Methisoprinol</i>
1	0,0000
2	0,0000

Tabel 8. Spesifisitas Pelarut

No.	Area Pelarut pada <i>Retention Time</i> (RT) <i>Methisoprinol</i>
1	0,0000
2	0,0000



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 9. Larutan Standar

No.	Konsentrasi (mg/mL)	<i>Inosine</i>		<i>4-Acetamido Benzoic Acid Salt</i>	
		<i>Retention Time (Menit)</i>	<i>Area</i>	<i>Retention Time (Menit)</i>	<i>Area</i>
1	0,5 as <i>Methisoprinol</i>	9,5	5523,3820	20,4	18042,1536
2		9,5	5522,1712	20,3	18081,7408
3		9,5	5521,6640	20,3	18120,5194
4		9,3	5522,8146	20,3	18082,8304
5		9,3	5519,5853	20,2	18070,9052
Rata-rata		9,4	5521,9234	20,3	18079,6299

Tabel 10. Larutan Sampel

No.	Konsentrasi (mg/mL)	Inosine		4-Acetamido Benzoic Acid Salt	
		Retention Time (Menit)	Area	Retention Time (Menit)	Area
1	0,5 as Methisoprinol	9,1	5528,5972	20,2	18249,3688
2		9,4	5520,5737	20,3	18237,0472
3		9,5	5523,3404	20,3	18270,4371
4		9,5	5537,7232	20,3	18287,9404
5		9,4	5535,7273	20,3	18312,8727
6		9,2	5515,5573	20,2	18196,6402
Rata-rata		9,4	5526,9199	20,3	18259,0511



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 11. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
Interferensi Fase Gerak	Memenuhi syarat (tidak ada interferensi dari fase gerak)	Tidak ada interferensi dari fase gerak
Interferensi Pelarut	Memenuhi syarat (tidak ada interferensi dari pelarut)	Tidak ada interferensi dari pelarut
<i>Retention Time</i>	Memenuhi syarat <i>(Retention time peak utama Methisoprinol pada larutan sampel sesuai dengan Retention time peak utama Methisoprinol pada larutan standar, yaitu $\pm 9,4$ untuk peak Inosine dan untuk peak 4-Acetamido Benzoic Acid Salt $\pm 20,3$ menit).</i>	<i>Retention time peak utama Methisoprinol pada larutan sampel sesuai dengan Retention time peak utama Methisoprinol pada larutan standar</i>

Kesimpulan: Spesifisitas memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

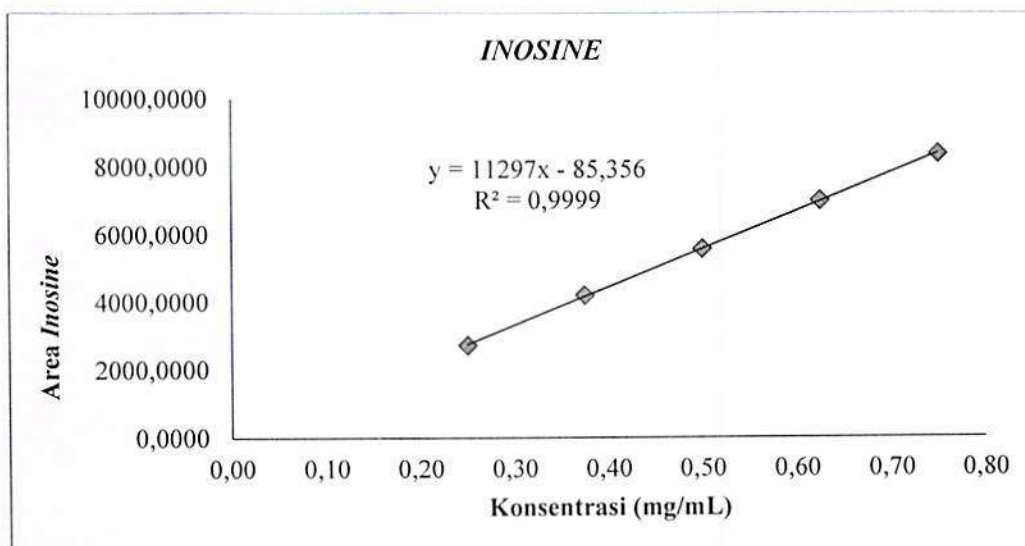
Tanggal Berlaku :

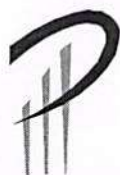
19 NOV 2025

8.3 Linieritas

Tabel 12. Larutan Linieritas *Inosine*

No.	Penimbangan Standar <i>Methisoprinol</i> (mg)	<i>Dilution</i> Standar	Konsentrasi		Area
			%	mg/mL	
1	25,0	100,00	50	0,250	2708,2045
2		66,67	75	0,375	4186,1036
3		50,00	100	0,500	5564,8540
4		40,00	125	0,625	6989,4701
5		33,33	150	0,750	8367,1654





PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

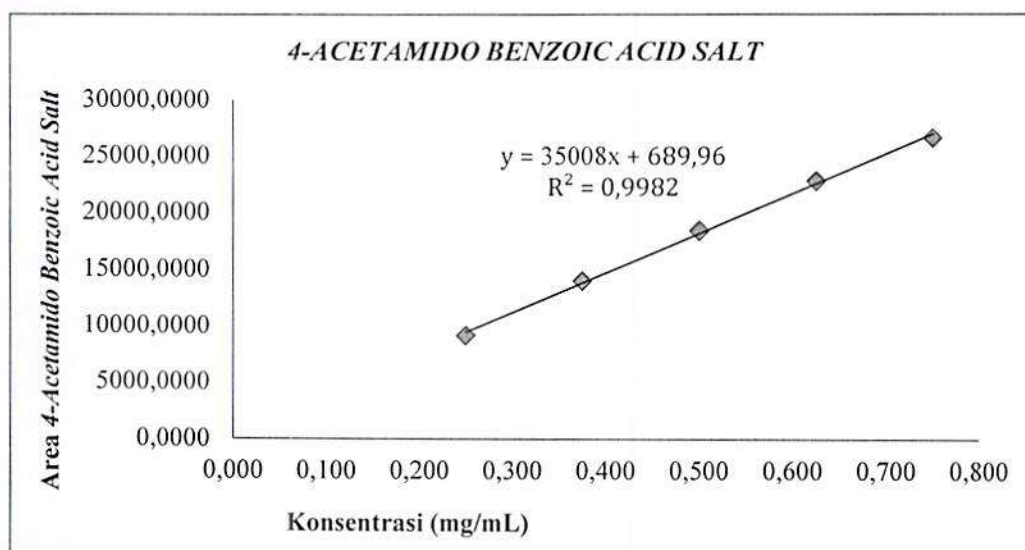
No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 13. Larutan Linieritas *4-Acetamido Benzoic Acid Salt*

No.	Penimbangan Standar <i>Methisoprinol</i> (mg)	Dilution Standar	Konsentrasi		Area
			%	mg/mL	
1	25,0 as <i>Methisoprinol</i>	100,00	50	0,250	9135,4025
2		66,67	75	0,375	13991,7225
3		50,00	100	0,500	18431,8931
4		40,00	125	0,625	22798,8752
5		33,33	150	0,750	26611,7954



Tabel 14. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Linieritas	Linieritas <i>Inosine</i> dan <i>4-Acetamido Benzoic Acid Salt</i>	0,999 dan 0,998	$\geq 0,990$

Kesimpulan: Uji linieritas memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

8.4 Akurasi

Tabel 15. Larutan Standar

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Tailing Factor	Retention Time (Menit)	Area	Tailing Factor
1	0,5 as Methisoprinol	9,5	5523,3820	1,1	20,4	18042,1536	1,0
2		9,5	5522,1712	1,1	20,3	18081,7408	1,0
3		9,5	5521,6640	1,1	20,3	18120,5194	1,0
4		9,3	5522,8146	1,1	20,3	18082,8304	1,0
5		9,3	5519,5853	1,1	20,2	18070,9052	1,0
Rata-rata		9,4	5521,9234	1,1	20,3	18079,6299	1,0
RSD (%)		NA	0,03%	NA	NA	0,16%	NA

Keterangan :

RSD (Relative Standard Deviation)

NA (Not Applicable)

Tabel 16. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Standar	%RSD area peak <i>Inosine</i> dan <i>4-Acetamido Benzoic Acid Salt</i>	0,03% dan 0,16%	$\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan <i>4-Acetamido Benzoic Acid Salt</i>	1,1 dan 1,0	$\leq 1,5$

Kesimpulan: Uji kesesuaian sistem larutan akurasi memenuhi syarat



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 17. Larutan Akurasi

No.	Konsentrasi (mg/mL)	Bobot Standar <i>Methisoprinol</i> RS (mg)	Faktor Pengenceran Standar (Ds)	Bobot Sampel <i>Methisoprinol</i> (mg)	Faktor Pengenceran Sampel (Du)
1	0,4	120,3	1000	125,0	313
2	0,5				250
3	0,6				208

Tabel 18. Larutan Akurasi *Inosine*

Konsentrasi		Area <i>Inosine</i>	Bobot Aktual (mg)	Bobot <i>Recovery</i> (mg)	<i>Recovery</i> (%)	<i>Rata-rata Recovery</i> (%)	
mg/mL	%						
0,4	80	4399,1170	125,0	124,5	99,6	99,7	
		4407,0323		124,7	99,8		
		4406,4209		124,7	99,7		
0,5	100	5513,2802		124,8	99,8	99,9	
		5515,6945		124,9	99,9		
		5515,4987		124,9	99,9		
0,6	120	6599,2448		124,5	99,6	99,3	
		6554,9459		123,7	98,9		
		6594,0174		124,4	99,5		
Minimum					98,9		
Maksimum					99,9		
Rata-rata					99,6		



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 19. Larutan Akurasi 4-Acetamido Benzoic Acid Salt

Konsentrasi		Area 4-Acetamido Benzoic Acid Salt	Bobot Aktual (mg)	Bobot Recovery (mg)	Recovery (%)	Rata-rata Recovery (%)	
mg/mL	%						
0,4	80	14642,5035	125,0	126,5	101,2	101,2	
		14634,7880		126,5	101,2		
		14638,7845		126,5	101,2		
0,5	100	18339,3375		126,8	101,4	101,5	
		18345,5211		126,8	101,5		
		18346,0538		126,8	101,5		
0,6	120	21917,5509		126,3	101,0	99,3	
		21302,3911		122,7	98,2		
		21399,7007		123,3	98,6		
Minimum					98,2		
Maksimum					101,5		
Rata-rata					100,7		

Tabel 20. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
Rata-rata Recovery larutan akurasi Inosine (%)	99,6%	98,0 – 102,0%
Rata-rata Recovery larutan akurasi 4-Acetamido Benzoic Acid Salt (%)	100,7	

Kesimpulan: Akurasi memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

8.5 Presisi Ripitabilitas

Tabel 21. Larutan Standar

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Tailing Factor	Retention Time (Menit)	Area	Tailing Factor
1	0,5 as Methisoprinol	9,5	5523,3820	1,1	20,4	18042,1536	1,0
2		9,5	5522,1712	1,1	20,3	18081,7408	1,0
3		9,5	5521,6640	1,1	20,3	18120,5194	1,0
4		9,3	5522,8146	1,1	20,3	18082,8304	1,0
5		9,3	5519,5853	1,1	20,2	18070,9052	1,0
Rata-rata		9,4	5521,9234	1,1	20,3	18079,6299	1,0
RSD (%)		NA	0,03%	NA	NA	0,16%	NA

Keterangan :

RSD (Relative Standard Deviation)

NA (Not Applicable)

Tabel 22. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Standar	%RSD area peak Inosine dan 4-Acetamido Benzoic Acid Salt	0,03% dan 0,16%	$\leq 1,04\%$
	Tailing Factor Inosine dan 4-Acetamido Benzoic Acid Salt	1,1 dan 1,0	$\leq 1,5$

Kesimpulan: Uji kesesuaian sistem memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 23. Larutan Presisi Rpitabilitas

No.	Konsentrasi (mg/mL)	Bobot Standar <i>Methisoprinol</i> RS (mg)	Faktor Pengenceran Standar (Ds)	Bobot Sampel <i>Methisoprinol</i> (mg)	Faktor Pengenceran Sampel (Du)
1	0,4	120,3	1000	125,0	313
2	0,5				250
3	0,6				208

Tabel 24. Larutan Presisi Rpitabilitas *Inosine*

Konsentrasi		Area <i>Methisoprinol</i>	Bobot Aktual (mg)	Bobot <i>Recovery</i> (mg)	<i>Recovery</i> (%)	<i>Rata-rata Recovery</i> (%)	<i>RSD Rata-rata Recovery</i> (%)	Rata-rata <i>RSD Seluruh Recovery</i> (%)		
mg/mL	%									
0,4	80	4399,1170	125,0	124,5	99,6	99,7	0,1	0,2		
		4407,0323		124,7	99,8					
		4406,4209		124,7	99,7					
0,5	100	5513,2802		124,8	99,8	99,9	0,0			
		5515,6945		124,9	99,9					
		5515,4987		124,9	99,9					
0,6	120	6599,2448		124,5	99,6	99,3	0,4			
		6554,9459		123,7	98,9					
		6594,0174		124,4	99,5					
Minimum					98,9					
Maksimum					99,9					
Rata-rata					99,6					



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 25. Larutan Presisi Ripitabilitas *4-Acetamido Benzoic Acid Salt*

Konsentrasi		Area <i>Methisoprinol</i>	Bobot Aktual (mg)	Bobot <i>Recovery</i> (mg)	<i>Recovery</i> (%)	<i>Rata-rata Recovery</i> (%)	<i>RSD Rata-rata Recovery</i> (%)	Rata-rata <i>RSD Seluruh Recovery</i> (%)		
mg/mL	%									
0,4	80	14642,5035	125,0	126,5	101,2	101,2	0,0	0,5		
		14634,7880		126,5	101,2					
		14638,7845		126,5	101,2					
0,5	100	18339,3375		126,8	101,4	101,5	0,0			
		18345,5211		126,8	101,5					
		18346,0538		126,8	101,5					
0,6	120	21917,5509		126,3	101,0	99,9	1,5			
		21302,3911		122,7	98,2					
		21399,7007		123,3	98,6					
Minimum					98,2					
Maksimum					101,5					
Rata-rata					100,7					

Tabel 26. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
Rata-rata RSD Seluruh Recovery Inosine (%)	0,2%	$\leq 2,0\%$
Rata-rata RSD Seluruh Recovery <i>4-Acetamido Benzoic Acid Salt</i> (%)	0,5%	

Kesimpulan: Presisi ripitabilitas memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

8.6 Presisi Antara

Tabel 27. Informasi Analisis dan Sampel

	Presisi Antara 1	Presisi Antara 2
Nama Analisis	Sri Komala	Jelly Martha Herlin
Tanggal Analisa	08 Oktober 2025	14 Oktober 2025
HPLC	Agilent/1260 - 600 bar (PI-AD-HPC-044)	Agilent/1260 - 600 bar (PI-AD-HPC-109)
Nama Bahan Baku	<i>Methisoprinol</i>	
Batch No.	MTP250225	
Manuf Date	April 2025	
Expiry Date	30 April 2028	

8.6.1 Presisi Antara Analisis 1

Tabel 28. Larutan Standar

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Tailing Factor	Retention Time (Menit)	Area	Tailing Factor
1	0,5 as Methisoprinol	9,5	5523,3820	1,1	20,4	18042,1536	1,0
2		9,5	5522,1712	1,1	20,3	18081,7408	1,0
3		9,5	5521,6640	1,1	20,3	18120,5194	1,0
4		9,3	5522,8146	1,1	20,3	18082,8304	1,0
5		9,3	5519,5853	1,1	20,2	18070,9052	1,0
Rata-rata		9,4	5521,9234	1,1	20,3	18079,6299	1,0
RSD (%)		NA	0,03%	NA	NA	0,16%	NA

Keterangan :

RSD (Relative Standard Deviation)

NA (Not Applicable)



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 29. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Standar	%RSD area <i>peak Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	0,03% dan 0,16%	$\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	1,1 dan 1,0	$\leq 1,5$

Kesimpulan: Uji kesesuaian sistem presisi 1 memenuhi syarat.

Tabel 30. Larutan Sampel

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Kadar on anhydrous basis (%)	Retention Time (Menit)	Area	Kadar on anhydrous basis (%)
1	0,5 as Methisoprinol	9,1	5528,5972	100,0	20,2	18249,3688	100,8
2		9,4	5520,5737	99,8	20,3	18237,0472	100,7
3		9,5	5523,3404	99,9	20,3	18270,4371	100,9
4		9,5	5537,7232	100,1	20,3	18287,9404	101,0
5		9,4	5535,7273	100,1	20,3	18312,8727	101,1
6		9,2	5515,5573	99,7	20,2	18196,6402	100,5
Rata-rata		9,4	5526,9199	99,9	20,3	18259,0511	100,9
RSD (%)		NA	0,2%	NA	NA	0,2%	NA

Keterangan :

RSD (*Relative Standard Deviation*)

NA (*Not Applicable*)

Kadar Air = 0,3%



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 31. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
Kadar <i>Inosine</i>	99,9%	95,0 – 105,0% on anhydrous basis
Kadar 4-Acetamido Benzoic Acid Salt	100,9%	

Kesimpulan: Presisi antara analisis 1 memenuhi syarat.

8.6.2 Presisi Antara Analisis 2

Tabel 32. Larutan Identifikasi

No.	Konsentrasi (mg/mL)	Inosine		
		Retention Time (Menit)	Area	Tailing Factor
1	0,12 as Inosine	9,0	5546,3673	1,1
2		9,1	5548,4183	1,1
3		9,0	5546,7021	1,1
Rata-rata		9,0	5547,1626	1,1
RSD (%)		NA	0,2%	NA



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 33. Larutan Standar

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Tailing Factor	Retention Time (Menit)	Area	Tailing Factor
1	0,5 as Methisoprinol	8,6	5299,7689	1,2	20,3	18907,0868	1,0
2		8,6	5299,6007	1,2	20,3	18940,6692	1,0
3		8,6	5300,5496	1,2	20,3	18903,3153	1,0
4		8,6	5297,9019	1,2	20,3	18900,1594	1,0
5		8,6	5298,9155	1,2	20,3	18906,2249	1,0
Rata-rata		8,6	5299,3473	1,2	20,3	18079,6299	1,0
RSD (%)		NA	0,02%	NA	NA	0,09%	NA

Keterangan :

RSD (*Relative Standard Deviation*)

NA (*Not Applicable*)

Tabel 34. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Standar	%RSD area peak <i>Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	0,02% dan 0,09%	$\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan 4- <i>Acetamido Benzoic Acid Salt</i>	1,2 dan 1,0	$\leq 1,5$

Kesimpulan: Uji kesesuaian sistem presisi 2 memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 35. Larutan Sampel

No.	Konsentrasi (mg/mL)	Inosine			4-Acetamido Benzoic Acid Salt		
		Retention Time (Menit)	Area	Kadar <i>on anhydrous basis</i> (%)	Retention Time (Menit)	Area	Kadar <i>on anhydrous basis</i> (%)
1	0,5 as <i>Methisoprinol</i>	8,7	5297,9736	99,8	20,3	18948,0351	100,1
2		8,7	5283,4996	99,6	20,3	19000,0530	100,3
3		8,8	5248,5595	98,9	20,3	19097,8735	100,8
4		8,8	5223,5045	98,4	20,3	19065,5239	100,7
5		8,8	5263,5953	99,2	20,3	19059,9266	100,6
6		8,8	5229,9267	98,6	20,2	19060,6579	100,6
Rata-rata		8,8	5257,8432	99,1	20,3	19038,6783	100,5
RSD (%)		NA	0,6%	NA	NA	0,3	NA

Keterangan :

RSD (Relative Standard Deviation)

NA (Not Applicable)

Kadar Air = 0,3%

Tabel 36. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
Kadar Inosine	99,1%	95,0 – 105,0% on anhydrous basis
Kadar 4-Acetamido Benzoic Acid Salt	100,5%	

Kesimpulan: Presisi antara analisis 2 memenuhi syarat.



PT. PHAROS INDONESIA

**LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

8.6.3 Komparasi Antara Presisi 1 dan Analisis 2

Tabel 37. Larutan Sampel Inosine

Analisis	Sri Komala	Jelly Martha Herlin
No.	Presisi Antara 1 (%)	Presisi Antara 2 (%)
1	100,0	99,8
2	99,8	99,6
3	99,9	98,9
4	100,1	98,4
5	100,1	99,2
6	99,7	98,6
Rata - rata	99,9	99,1
RSD (%)	0,0	0,6
Rata – rata 12 data (%)	100	
RSD 12 data (%)	0,6	

Keterangan :

RSD (Relative Standard Deviation)



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 38. Larutan Sampel 4-Acetamido Benzoic Acid Salt

Analisis	Sri Komala	Jelly Martha Herlin
No.	Presisi Antara 1 (%)	Presisi Antara 2 (%)
1	100,0	99,8
2	99,8	99,6
3	99,9	98,9
4	100,1	98,4
5	100,1	99,2
6	99,7	98,6
Rata - rata	99,9	99,1
RSD (%)	0,0	0,3
Rata – rata 12 data (%)	100,7	
RSD 12 data (%)	0,3	

Keterangan :

RSD (Relative Standard Deviation)

Tabel 39. Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan
Larutan Presisi 1 dan 2	Kadar <i>Inosine</i>	100,0%	95,0 – 105,0% <i>on anhydrous basis</i>
	Kadar 4-Acetamido Benzoic Acid Salt	100,7%	
	%RSD area <i>peak Inosine</i> antar analisis	0,6%	≤ 2,0%
	%RSD area <i>peak 4-Acetamido Benzoic Acid Salt</i> antar analisis.	0,3%	

Kesimpulan : Komparasi presisi antara 1 dan presisi antara 2 (antar analisis) memenuhi syarat.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :
19 NOV 2025

8.7 Robustness

Tabel 40. Larutan Standar *Methisoprinol*

No.	Interval Waktu (Jam)	Inosine			4-Acetamido Benzoic Acid Salt		
		Area Standar Akhir	Area Standar Awal (0 jam)	Recovery Robustness Larutan Standar (%)	Area Standar Akhir	Area Standar Awal (0 jam)	Recovery Robustness Larutan Standar (%)
1.	3	5508,3746	5514,5242	99,9	18488,9607	18473,1525	100,1
2.	6	5515,1570		100,0	18553,7890		100,4
3.	9	5528,2855		100,2	18602,3556		100,6
4.	12	5536,4923		100,4	18567,5041		100,5
5.	24	5506,4851		99,9	18468,4331		100,0
Rata-rata				100,1	NA	NA	100,3

Tabel 41. Larutan Sampel *Methisoprinol*

No.	Interval Waktu (Jam)	Inosine			4-Acetamido Benzoic Acid Salt		
		Area Standar Akhir	Area Standar Awal (0 jam)	Recovery Robustness Larutan Standar (%)	Area Standar Akhir	Area Standar Awal (0 jam)	Recovery Robustness Larutan Standar (%)
1.	3	5662,8312	5661,1149	100,0	18384,2507	18421,4327	99,8
2.	6	5663,4307		100,0	18323,6671		99,5
3.	9	5662,2861		100,0	18371,4977		99,7
4.	12	5662,8598		100,0	18448,0893		100,1
5.	24	5686,2192		100,4	18543,1061		100,7
Rata-rata				100,1	NA	NA	100,0



PT. PHAROS INDONESIA

**LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU**

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

Tabel 42. Kriteria Penerimaan

Parameter	Hasil	Kriteria Penerimaan
%Recovery Robustness larutan standar <i>Inosine</i> dan <i>4-Acetamido Benzoic Acid Salt</i>	100,1% dan 100,3%	98,0 – 102,0%
%Recovery Robustness larutan sampel <i>Inosine</i> dan <i>4-Acetamido Benzoic Acid Salt</i>	100,1% dan 100,0%	

Kesimpulan : *Robustness* memenuhi syarat, larutan standar dan larutan sampel stabil hingga 24 jam.

8.8. Range

Range dalam validasi metode analisis ini adalah 50,0 – 150,0%.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :

19 NOV 2025

9. DISKUSI

Telah dilakukan validasi metode analisis kadar bahan baku *Methisoprinol* dimana parameter uji kesesuaian sistem memvalidasi bahwa sistem kromatografi dapat digunakan untuk analisa sesuai acuan monografi *in house method* mengacu *analytical method of manufacturer* tahun 2023 (ABC Farmaceutici), dengan hasil memenuhi syarat sesuai Tabel 6.

Spesifisitas untuk memastikan tidak ada interferensi dari pelarut dan fase gerak terhadap waktu retensi dari *Methisoprinol* dan memastikan kesesuaian waktu retensi *peak Methisoprinol* pada larutan sampel dengan waktu retensi *peak Methisoprinol* pada larutan standar, dengan hasil memenuhi syarat sesuai Tabel 11.

Linieritas dilakukan untuk melihat hubungan yang linier antara respon analisis dan konsentrasi analit dalam rentang penggunaan metode analisis berdasarkan linieritas (R^2) $\geq 0,990$ dengan hasil memenuhi syarat sesuai Tabel 14.

Akurasi dilakukan untuk melihat *recovery* dari konsentrasi zat aktif yang telah diketahui dengan 3 level konsentrasi 80%, 100% dan 120%. %*Recovery* dari masing-masing level konsentrasi telah dievaluasi dengan hasil memenuhi syarat sesuai Tabel 20.

Presisi ripitabilitas dilakukan untuk memastikan %*RSD* dari *recovery* larutan akurasi dengan 3 level konsentrasi mendapatkan hasil memenuhi syarat sesuai Tabel 26.

Presisi antara dievaluasi untuk memvalidasi kadar bahan baku *Methisoprinol* oleh 2 analis sesuai acuan monografi *in house method* mengacu *analytical method of manufacturer* tahun 2023 (ABC Farmaceutici), dengan hasil memenuhi syarat sesuai Tabel 31 untuk hasil % kadar presisi antara analis 1, Tabel 36 untuk hasil % kadar presisi antara analis 2, dan Tabel 39 untuk hasil %*RSD* antar analis presisi antara 1 dan presisi antara 2.

Robustness dilakukan untuk melihat kestabilan zat aktif pada kondisi yang berbeda (interval waktu) tanpa ada perbedaan yang bermakna dengan hasil memenuhi syarat sesuai Tabel 42.

Range dilakukan untuk melihat rentang konsentrasi analit terkecil hingga terbesar pada parameter linieritas, akurasi, dan presisi dengann hasil memenuhi spesifikasi yang ditetapkan yaitu 50,0 – 150,0%.

10. KESIMPULAN

Metode analisis kadar bahan baku *Methisoprinol* dinyatakan valid sesuai tujuannya.

11. REVALIDASI

Revalidasi dilakukan apabila terdapat perubahan pada monografi acuan, sistem kromatografi dan konsentrasi larutan. Pengujian revalidasi dapat dilakukan validasi penuh atau validasi parsial sesuai justifikasi.



PT. PHAROS INDONESIA

LAPORAN VALIDASI METODE
ANALISIS KADAR DALAM
BAHAN BAKU

METHISOPRINOL

No. :
LV/AD/BB/2025/009.1.00

Tanggal Berlaku :
19 NOV 2025

RIWAYAT PERUBAHAN

No.	No. Dokumen	Tgl. Berlaku	Menggantikan		Keterangan
			Dokumen No.	Tgl. Berlaku	
1.	LV/AD/BB/2025/ 009.1.00	19 NOV 2025	NA	NA	Dokumen perdana mengacu <i>in house method</i> mengacu <i>analytical method</i> <i>of manufacturer tahun</i> <i>2023 (ABC Farmaceutici)</i>

LAPORAN VALIDASI METODE ANALISIS BAHAN BAKU
KADAR METHISOPRIMOL

Tanggal Analisis : 08 Oktober 2025 - 12 Oktober 2025

AD Scientist : Sri Komala

Parameter : UKS (Peak Identifikasi dan Larutan standar), Spesifikasi, Linearitas, Akurasi, Presisi Antara 1, Repeatables

Informasi Reference Standard

Nama : Methisoprimol
No Lot : AB0122678
Potensi : 99.56%
Expired date : Current Lot
Manufacturer : BPFI

Nama : Inosine
No Lot : 2023-CPO-018
Potensi : 99.94%
Expired date : Current Lot
Manufacturer : BPFI

Nama : Methisoprimol
No. Batch : MHTP240225
Expired date : 30 April 2028
Manufacturer : Ucalphos

Informasi Sampel

PEAK IDENTIFIKASI

No.	Inosine RS (mg)	Dilution Inosine RS	Kons. Inosine RS (mg/ml)	Retention Time (Menit)	Tailing Factor	Area Inosine
1	120	1000	0.120	9.3	1.1	5439.3889
2				9.3	1.1	5436.0212
3				9.3	1.1	5437.8306
Rata-rata				9.3	1.1	5437.7469
%RSD						0.03%
Syarat					0.8 - 1.5	<1.04 %

SPESIFISITAS

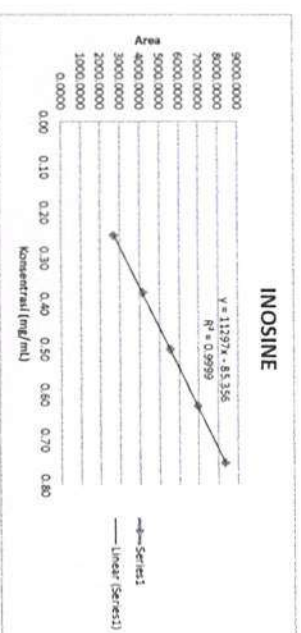
Spesifisitas	Area
Polutan	0.000
Fase Derak	0.000

LABATAN STANDAR

ANALISIS KANDUNGAN METISOPRIMOL									
No.	Methisoprimol RS (mg)	Dilution Methisoprimol RS	Kons. Methisoprimol RS (mg/mL)	Retention Time (Menit)	Tailing Factor	Area Inosine (Menit)	Retention Time (Menit)	Tailing Factor	Area 4-ticantando benzoic acid salt
1	10	20	0.5	9.5	1.1	5523.3820	20.4	1.0	18042.1536
2				9.5	1.1	5522.1712	20.3	1.0	18081.7408
3				9.5	1.1	5521.6640	20.3	1.0	18120.5194
4				9.3	1.1	5522.8146	20.3	1.0	18082.8504
5				9.3	1.1	5519.5853	20.2	1.0	18070.8052
Rata-rata				9.4	1.1	5521.9214	20.3	1.0	18079.6299
%RSD						0.03%			0.16%
Syarat					0.8 - 1.5	≤1.04 %		0.8 - 1.5	≤1.04 %

LINEARITAS

INOSINE				
Nama	Konsentrasi (mg/mL)	Area	Area Rata-Rata	% RSD Area
Linertias 50%	0.25	2707.6514	2708.2045	0.1%
		2712.2655		
		2704.6966		
Linertias 75%	0.375	4188.8382	4186.1036	0.1%
		4187.4344		
		4182.0382		
Linertias 100%	0.5	5563.2206	5564.8540	0.0%
		5565.9495		
		5567.3919		
Linertias 125%	0.625	6986.2981	6989.4701	0.0%
		6991.1170		
		6990.9951		
Linertias 150%	0.75	8350.8053	8367.1654	0.2%
		8369.1084		
		8381.5826		
R ²		1.000		
Syarat		≥ 0.990		



4-ACETAMIDO BENZOIC ACID SALT					
Name	Konzentrat (mg/ml)	Area	Area Ratio-Ratio	% RSD Area	
Linertias 50%	0.250	9125.5575	9135.4025	0.2%	
		9155.7477			
		9124.9034			
Linertias 75%	0.375	13993.0658	13991.7225	0.0%	
		13986.4777			
		13995.7271			
Linertias 100%	0.500	18437.4058	18431.8931	0.0%	
		18434.6121			
		18433.6645			
Linertias 125%	0.625	22782.4779	22798.8752	0.1%	
		22817.3500			
		22796.7886			
Linertias 150%	0.750	26670.1942	26611.7954	0.2%	
		26589.8407			
		26575.8512			
R ²		0.998			
Standard		≥ 0.990			

• LARUTAN STANDAR

• AKURASI DAN PRESISI RAPTABILITAS

Perhitungan:

$$\text{Bobot Recovery} = \frac{ru \times Du \times Ws}{rs \times Ds}$$

$$\% \text{Recovery} = \frac{\text{Bobot recovery} \times 100\%}{\text{Bobot aktual}}$$

Keterangan:

ru = Respon area peak *inosine* dan *4-acetamidobenzoic acid salt* dari larutan standar
rs = Respon area peak *inosine* dan *4-acetamidobenzoic acid salt* dari larutan standar
Du = Faktor pengenceran dari larutan standar
Ds = Faktor pengenceran dari larutan standar
Ws = Bobot penambahan dari larutan standar (mg)

• PREKSI ANTARA I INOSINE

INOSINE										
No	Ws	Ds	rs	Retention Time (Menit)	Bobot Sampel (mg)	Du	ru	Retention Time (Menit)	Kadar air (%)	Kadar (%)
1	10	20	5523.3820	9.5	25.0	50	5528.5972	9.1	0.3	100.0%
2			5522.1712	9.5	25.0		5520.5737	9.4		99.8%
3			5521.6640	9.5	25.0		5523.3404	9.5		99.9%
4			5522.8146	9.3	25.0		5537.7232	9.5		100.1%
5			5519.5853	9.3	25.0		5535.7273	9.4		100.1%
6			-	-	25.0		5515.5573	9.2		99.7%
Rata-rata			5521.9234	9.4	25.0		5526.9199	9.4		99.9%
% RSD			0.0%				0.2%			0.0%
Start										95.0 - 105.0

Syarat

LACTAMINO BENZOIC ACID SALT

L-ACETAMIDO BENZOIC ACID SALT										
No	Ws	Ds	rs	Retention Time (Menit)	Bobot Sampel (mg)	Du	ru	Retention Time (Menit)	Kadar air (%)	Kadar (%)
1	10	20	18042.1536	20.4	25.0	50	18249.3688	20.2	0.3	100.8%
2			18081.7408	20.3	25.0		18237.0472	20.3		100.7%
3			18120.5194	20.3	25.0		18270.4371	20.3		100.9%
4			18082.8304	20.3	25.0		18287.9404	20.3		101.0%
5			18070.9052	20.2	25.0		18312.8727	20.3		101.1%
6			-	-	25.0		18196.6402	20.2		100.5%
Rata-rata			18079.6299	20.3	25.0		18259.0511	20.3		100.9%
% RSD			0.0	0.0	0.0		0.2	0.3		0.0%
Serial										
										95.0 - 105.0

Syarat

Perhitungan

$$\% \text{Kadar} = \frac{ru}{rs} \times \frac{Ws}{Ws} \times \frac{P}{(100 - KF)} \times \frac{Du}{Ds} \times 100$$

Keterangan:

ru = Respon area peak *inosine* dan *4-acetamidobenzoic acid salt* dari larutan sampel
rs = Respon area peak *inosine* dan *4-acetamidobenzoic acid salt* dari larutan standar
Ws = Bobot penambahan dari larutan standar (mg)
Ws = Bobot penambahan dari larutan sampel (mg)
P = Potensi *Methasprinol* RS (%)
Du = Faktor pengenceran dari larutan sampel
Ds = Faktor pengenceran dari larutan standar
KF = Kadar air sampel

***ROBUSTNESS**

A. ROBUSTNESS 0 JAM

Lantian Standar					
No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt
1	0.5	10.2	5515.6520	20.9	18401.9268
2		10.2	5514.0963	20.9	18473.2852
3		10.2	5513.8244	21.0	18484.2374
Rata-rata			5514.5242		18473.1525
% RSD			0.0%		0.1%

Lantian Sampel					
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt
1	0.5	9.2	5659.7099	20.2	18431.5469
2		9.1	5660.3946	20.2	18422.4117
3		9.2	5663.2492	20.2	18410.3396
Rata - rata			5661.1149		18421.4327
% RSD			0.0%		0.1%

B. ROBUSTNESS 3 JAM

Lantian Standar							
No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	10.3	5506.0427	99.8%	21	18425.5220	99.7%
2		10.2	5508.7485	99.9%	21	18505.9230	100.2%
3		10.3	5510.2326	99.9%	20.9	18535.4271	100.3%
Rata - rata			5508.3746	99.9%		18488.9607	100.1%
% RSD			0.0%	0.0%		0.3%	0.3%

Lantian Sampel							
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	9.6	5656.3189	99.9%	20.3	18398.5556	99.9%
2		9.5	5663.7933	100.0%	20.3	18378.1601	99.8%
3		9.5	5668.3813	100.1%	20.4	18376.0263	99.8%
Rata - rata			5662.8312	100.0%		18384.2507	99.8%
			0.1%	0.1%		0.1%	0.1%

C. ROBUSTNESS 6 JAM

C. RUMESTINZA 9.3.2019							
Lantian Standar							
No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	10.0	5507.3649	99.9%	20.7	18499.9874	100.1%
2		10.0	5515.0930	100.0%	20.7	18576.0795	100.6%
3		9.9	5522.9970	100.2%	20.6	18383.3000	100.6%
Rata - rata			5515.1570	100.0%		18553.7890	100.4%
% RSD			0.1%	0.1%		0.3%	0.3%

Lantian Sampel							
% RSD				Kons. Sampel			
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	9.8	5659.4607	100.0%	20.5	18347.6351	99.6%
2		9.8	5664.4169	100.1%	20.6	18315.2083	99.4%
3		9.9	5666.4144	100.1%	20.6	18308.1580	99.4%
Rata - rata			5663.4307	100.0%		18323.6671	99.5%
% RSD			0.1%	0.1%		0.1%	0.1%

D. ROBUSTNES 9 JAM

Lanjutan Standar							
No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	9.7	5520.6853	100.1%	20.5	18570.0120	100.4%
2		9.6	5531.4588	100.3%	20.4	18617.9411	100.7%
3		9.5	5532.7123	100.3%	20.4	18619.1136	100.7%
Rata - rata			5528.2855	100.2%		18602.3856	100.6%
% RSD			0.1%	0.1%		0.2%	0.2%

Lanjutan Sampel							
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	10	5663.1857	100.0%	20.7	18337.0249	99.5%
2		10.1	5660.0546	100.0%	20.7	18372.5771	99.7%
3		10.0	5663.6178	100.0%	20.8	18404.8910	99.9%
Rata - rata			5662.2861	100.0%		18371.4977	99.7%
% RSD			0.0%	0.0%		0.2%	0.2%

E. ROBUSTNES 12 JAM

Lanjutan Standar							
No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	9.7	5539.2477	100.4%	20.5	18578.5777	100.6%
2		9.7	5536.1051	100.4%	20.6	18567.4911	100.5%
3		9.7	5534.1242	100.4%	20.6	18556.4434	100.5%
Rata - rata			5536.4923	100.4%		18567.5041	100.5%
% RSD				0.0%		0.1%	0.1%

Lanjutan Sampel							
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	10.2	5656.4327	99.9%	20.8	18402.8792	99.9%
2		10.1	5664.9486	100.1%	20.9	18462.8813	100.2%
3		10.1	5667.1981	100.1%	20.9	18478.5075	100.3%
Rata - rata			5662.8598	100.0%		18448.0893	100.1%
% RSD			0.1%	0.1%		0.2%	0.2%

F. ROBUSTNES 24 JAM

No.	Kons. Standar (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	10.3	5502.1338	99.8%	21	18459.5461	99.9%
2		10.2	5508.8619	99.9%	21	18472.3569	100.0%
3		10.1	5508.4596	99.9%	20.9	18473.4162	100.0%
Rata-rata			5506.4851	99.9%		18468.4331	100.0%
% RSD			0.1%	0.1%		0.0%	0.0%

Lanjutan Sampel							
No.	Kons. Sampel (mg/mL)	Retention Time (Menit)	Area Ilosine	%Recovery	Retention Time (Menit)	Area 4-Acetamido Benzoic Acid Salt	%Recovery
1	0.5	9.4	5675.9402	100.3%	20.4	18535.0348	100.6%
2		9.5	5688.6521	100.5%	20.4	18521.4175	100.5%
3		9.5	5694.0652	100.6%	20.4	18572.8659	100.8%
Rata - rata			5686.2192	100.4%		18541.1061	100.7%
% RSD			0.2%	0.2%		0.1%	0.1%

Rumus Perhitungan Standar :

$$\% \text{Recovery Standar} = \frac{rs \text{ jam ke-}(t)}{rs \text{ jam ke-}0} \times 100\%$$

$$\% \text{Recovery Sampel} = \frac{ru \text{ jam ke-}(t)}{ru \text{ jam ke-}0} \times 100\%$$

Keterangan:

rs = Respon area peak *inosine* dan *4-acetamido benzoic acid* dari larutan standar
 ru = Respon area peak *inosine* dan *4-acetamido benzoic acid* dari larutan sampel

Larutan Standar

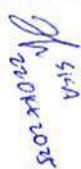
No	Robustness (jam)	%Recovery of <i>Inosine</i>	%Recovery of <i>4-Acetamido Benzoic Acid Salt</i>
1	3	99.9%	100.1%
2	6	100.0%	100.4%
3	9	100.2%	100.6%
4	12	100.4%	100.5%
6	24	99.9%	100.0%
Rata Rata %Recovery		100.1%	100.3%
Syarat		98.0 - 102.0%	98.0 - 102.0%

Larutan Sampel

No	Robustness (jam)	%Recovery of <i>Inosine</i>	%Recovery of <i>4-Acetamido Benzoic Acid</i>
1	3	100.0%	99.8%
2	6	100.0%	99.5%
3	9	100.0%	99.7%
4	12	100.0%	100.1%
6	24	100.4%	100.7%
Rata Rata %Recovery		100.1%	100.6%
Syarat		98.0 - 102.0%	98.0 - 102.0%

Kriteria Penerimaan

Komponen	Parameter	Hasil	Kriteria Penerimaan	Kesimpulan	
Larutan Standar	% RSD <i>Isoime</i>	0.03%		Memenuhi Syarat	
	% RSD 4-Acetamido benzoic acid	0.16%	$\leq 1.04\%$	Memenuhi Syarat	
	Tailing factor <i>Isoime</i>	1.1		Memenuhi Syarat	
	Tailing Factor 4-Acetamido benzoic acid	1.0	0.8 - 1.5	Memenuhi Syarat	
Larutan Spesifitas	Interferensi Pelekat	Tidak ada Interferensi	Tidak ada Interferensi	Memenuhi Syarat	
	Interferensi Fase Gerak	Tidak ada Interferensi	Tidak ada Interferensi	Memenuhi Syarat	
Lineritas	R^2 <i>Isoime</i>	1.000		Memenuhi Syarat	
	R^2 4-Acetamido benzoic acid	0.998	≥ 0.990	Memenuhi Syarat	
Larutan Akurasi dan Presisi Repetabilitas	% Recovery <i>Isoime</i>	99.6%		Memenuhi Syarat	
	% Recovery 4-Acetamido benzoic acid	100.7%	98.0 - 102.0%	Memenuhi Syarat	
	% RSD <i>Isoime</i>	0.2%		Memenuhi Syarat	
	% RSD 4-Acetamido benzoic acid	0.5%	$\leq 2.0\%$	Memenuhi Syarat	
	Kadar <i>Isoime</i>	99.9%		Memenuhi Syarat	
Presisi antara 1	Kadar 4-Acetamido benzoic acid	100.9%	95.0 - 105.0 %	Memenuhi Syarat	
	Standar <i>Isoime</i>	100.1%		Memenuhi Syarat	
	Standar	100.3%	98.0 - 102.0 %	Memenuhi Syarat	
Robustness	4-Acetamido benzoic acid	100.1%		Memenuhi Syarat	
	Sampel <i>Isoime</i>	100.1%		Memenuhi Syarat	
	4-Acetamido benzoic acid	100.0%	98.0 - 102.0 %	Memenuhi Syarat	

Dilakukan oleh :	Diperiksa oleh :	Ditetujui oleh :
		
23/04/2025	23/11/25	25/11/25
	Pary	Pary

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file: E:\CDSP\Project\ADAD 2025\October 2025\Results\VMA
Methisopronolol091025_VMA_Methisopronolol_Kadar_MoA.rsl;SPESIFISITAS
PELARUT05P1-A2scientist.dx

Sample name: SPESIFISITAS PELARUT

Instrument: LC 1260 UV

Injection: 1 of 1

Injection date: 2025-10-10 00:58:53+07:00

Injection volume: 20.000

Acq. method: Methisopronolol_Kadar_MoA.amx

Acq. operator: scientist

Column name: Purosphar RP 18
Endcapped (K53)

Analysis method: PMA_VMA
Methisopronolol_MoA.pmx

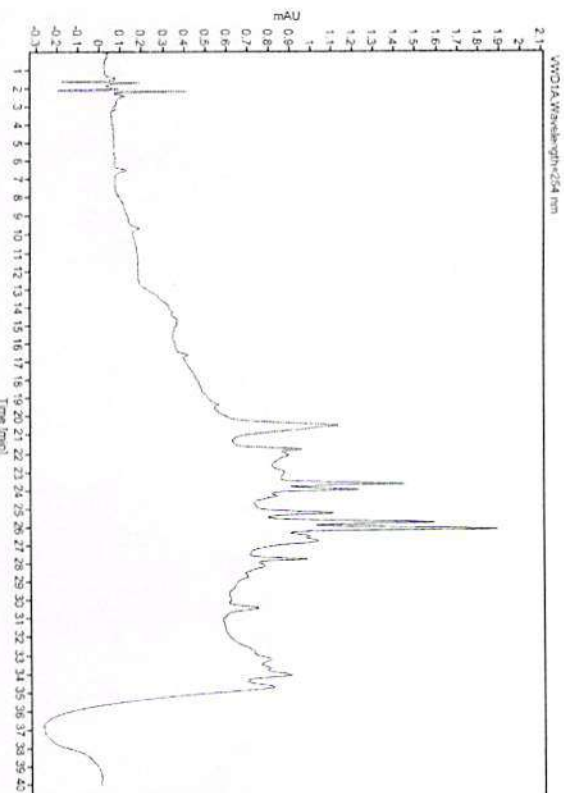
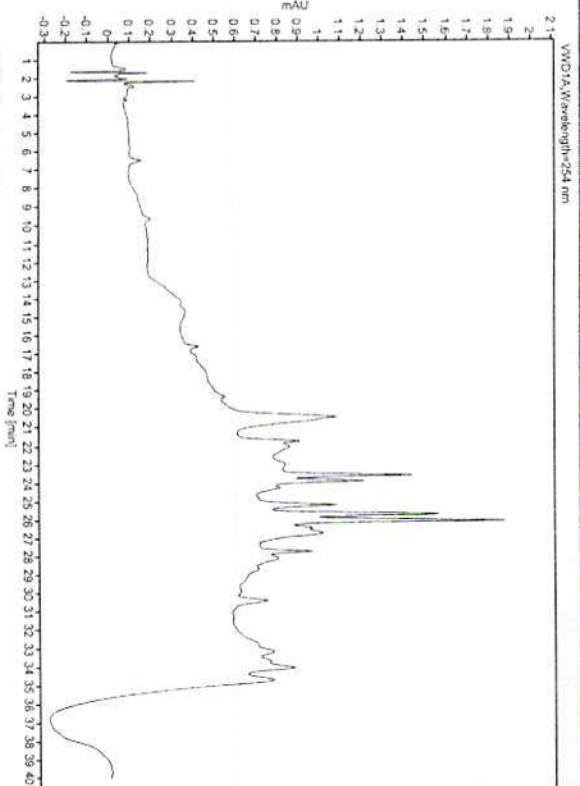
Column Serial No 310767

Last changed: 2025-10-17 19:09:45+07:00

Column Length : 150.0 mm

Location: P1-A2

Column Diameter : 4.6 mm



SKA
14.10.2025

Cross Sequence Summary Report

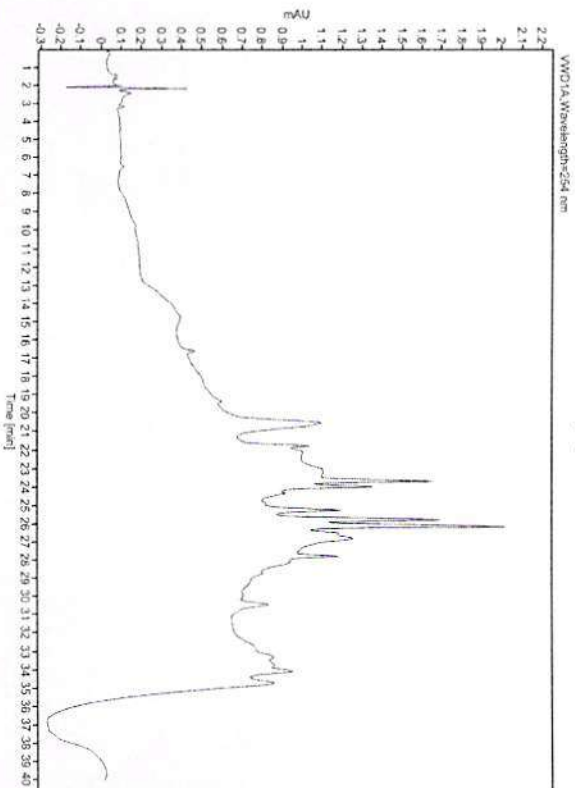
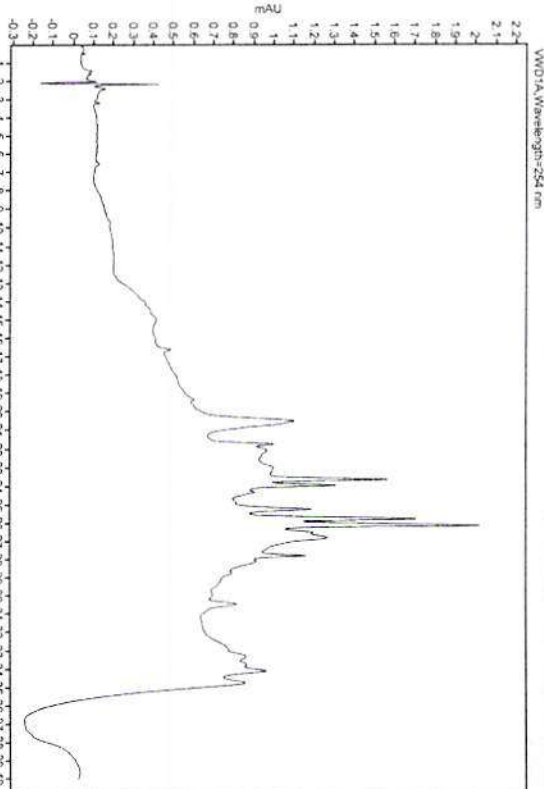


Cross Sequence Summary Report



Data file: E:\CDSP\jects\ADAD 2025\October 2025\Results\VMA_MetHisopinol\091025_VMA_MetHisopinol_Kadar_MoA.rst\SPEFISITAS FASE GERAK08P1-A3scientist.d

Sample name:	SPEFISITAS FASE GERAK	Injection:	1 of 1
Instrument:	LC 1260 UV	Injection volume:	20.000
Injection date:	2025-10-10 03:02:48-07:00	Acq. operator:	scientist
Acq. method:	MetHisopinol_Kadar_MoA.amx	Column name:	Purosphere RP 18 Endcapped (K53)
Analysis method:	*PM_VMA MetHisopinol_MoA.pmx	Column Serial No	310767
Last changed:	2025-10-17 19:09:45-07:00	Column Length :	150.0 mm
Location:	P1-A3	Column Diameter :	4.6 mm



Cross Sequence Summary Report



Data file:

E:\CDSP\Project\AD\AD 2025\October 2025\Resus\VMA
Methisopinol\091025_VMA_Methisopinol_Kadar_MoA.rsin\INOSINE11P2-
A4scientist1.d

Sample name:

INOSINE

Injection :

1 of 1

Instrument:

LC 1260 UV

Injection volume :

20.0 µL

Injection date:

2025-10-10 05:06:40-07:00

Acq. operator :

scientist

Acq. method:

Methisopinol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

*PM_VMA_Methisopinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:06-07:00

Column Length :

150.0 mm

Location:

P2-A4

Column Diameter :

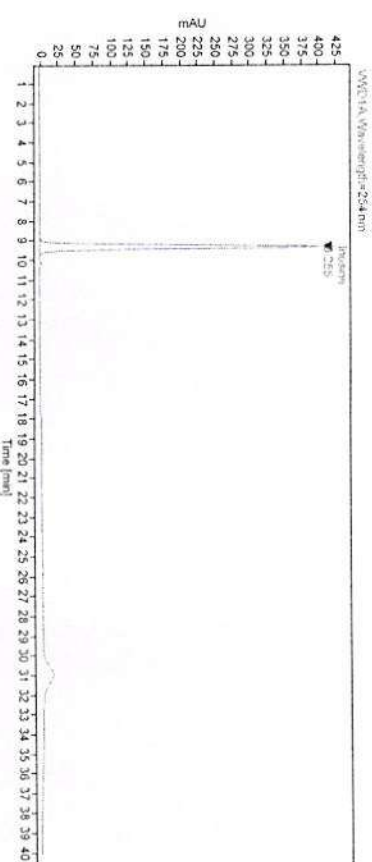
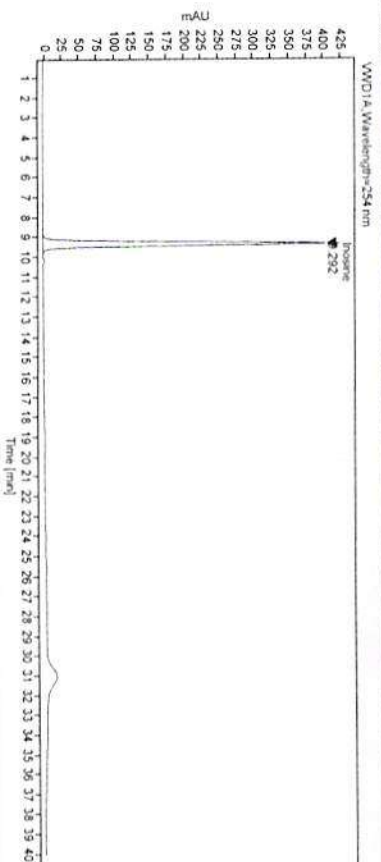
4.6 mm

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Date
INOSINE	9.3	406.485	5439.3869		1.08112	10/10/2025 05:06:40
INOSINE	9.3	406.692	5436.0212		1.07829	10/10/2025 05:47:58
INOSINE	9.3	406.785	5437.8306		1.07770	10/10/2025 06:29:16
		Mean	5437.7459			
		Std Dev.	1.6854			
		%RSD	0.0310			

Cross Sequence Summary Report



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\projects\ADAO 2025\October 2025\Results\VMA
Methisopropinol_091025_VMA_Methisopropinol_Kadar_MoA.rsl\STANDARD1SP1-
A4scientist.d

Sample name:

STANDARD

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-10 07:51:51+07:00

Acq. operator:

scientist

Acq. method:

Methisopropinol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

*PM_VMA
Methisopropinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-A4

Column Diameter :

4.6 mm

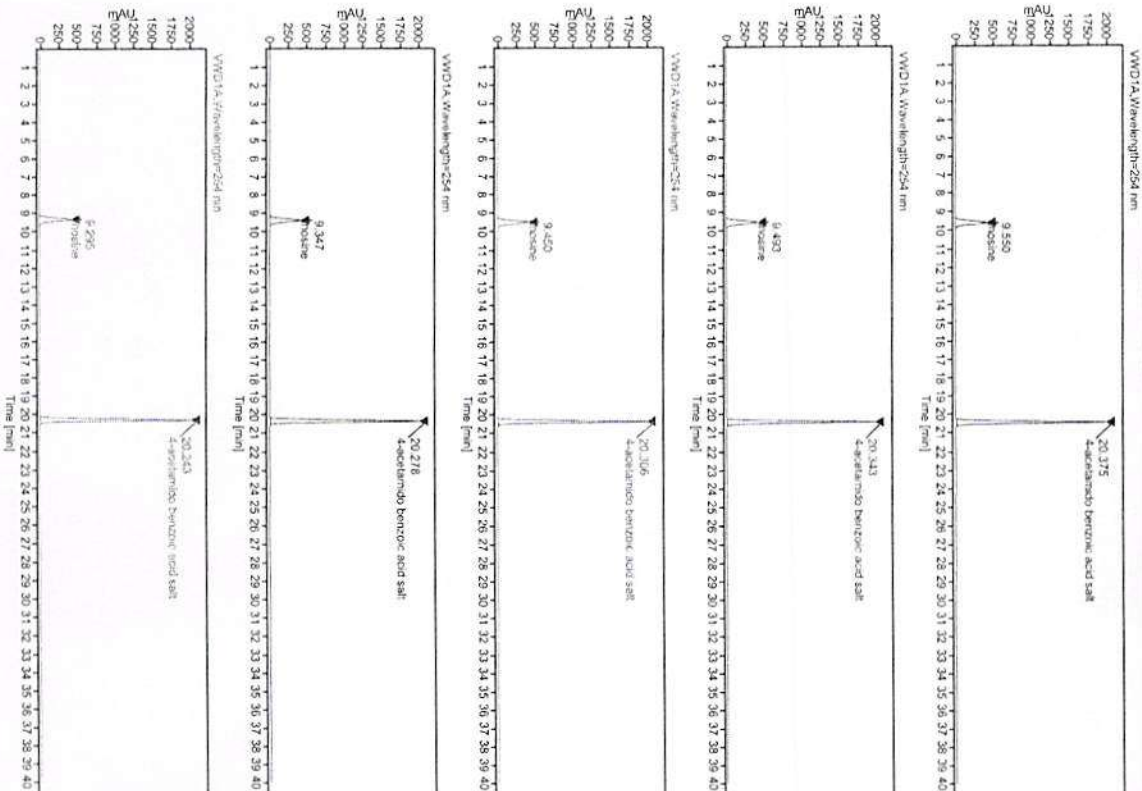
Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD	20.4	1988.4	18042.1536	36.4	1.02618	10/10/2025 07:51:51
STANDARD	20.3	1984.1	18081.7408	36.3	1.01978	10/10/2025 08:33:09
STANDARD	20.3	1995.9	18120.5194	36.6	1.03214	10/10/2025 09:14:25
STANDARD	20.3	2004.5	18082.8304	36.8	1.03377	10/10/2025 09:55:43
STANDARD	20.2	2011.5	18070.9052	36.9	1.02324	10/10/2025 10:37:00
		Mean	18079.6299			
		Std Dev.	28.1391			
		%RSD	0.1556			

Name: Ilosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD	9.5	418.3	5523.3820		1.06979	10/10/2025 07:51:51
STANDARD	9.5	416.1	5522.1712		1.06013	10/10/2025 08:33:09
STANDARD	9.5	418.9	5521.6640		1.07209	10/10/2025 09:14:25
STANDARD	9.3	417.0	5522.8146		1.06222	10/10/2025 09:55:43
STANDARD	9.3	416.9	5519.5853		1.07482	10/10/2025 10:37:00
		Mean	5521.9274			
		Std Dev.	1.4592			
		%RSD	0.0264			

SKA
15/10/2025



Cross Sequence Summary Report



Data file:

ENCDSProjectADAD 2025\October 2025\Results\VMA
Methisoprinol_091025_VMA_Methisoprinol_Kadar_MoA.rsl\LINERTAS 503SP1-
C\scientist1.dx

Sample name:

LINERTAS 50

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-10 21:37:50+07:00

Acq. operator:

scientist

Acq. method:

Methisoprinol_Kadar_MoA.amx

Column name:

Purosphare RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisoprinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-C1

Column Diameter :

4.6 mm

Name: 4-acetamidobenzoic acid salt

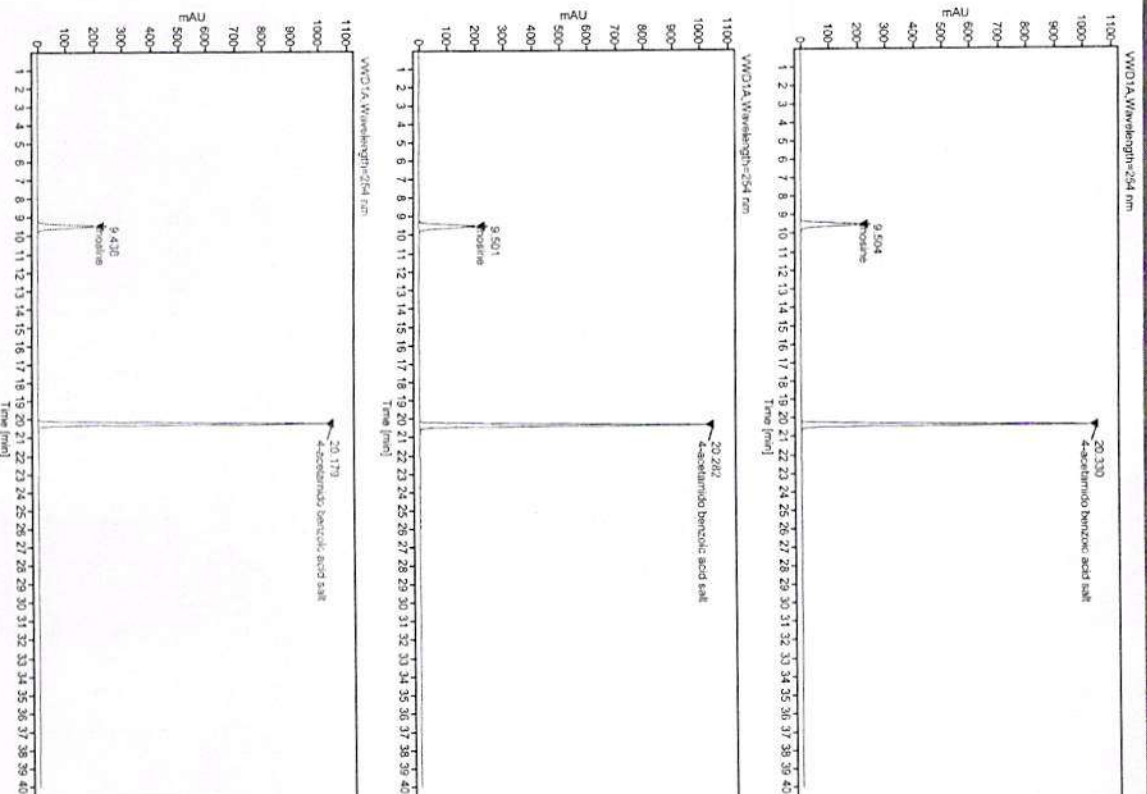
Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 50	20.3	1023.2	9125.5575	37.0	1.02549	10/10/2025 21:37:50
LINERTAS 50	20.3	1019.5	9155.7477	36.4	1.03836	10/10/2025 22:19:10
LINERTAS 50	20.2	1023.9	9124.9024	36.5	1.03107	10/10/2025 23:00:29
		Mean	9135.4025			
		Std Dev.	17.6225			
		%RSD	0.1929			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 50	9.5	207.5	2707.6514		1.04688	10/10/2025 21:37:50
LINERTAS 50	9.5	204.9	2712.2655		1.04664	10/10/2025 22:19:10
LINERTAS 50	9.4	204.9	2704.6966		1.04768	10/10/2025 23:00:29
		Mean	2708.2045			
		Std Dev.	3.8147			
		%RSD	0.1409			

Cross Sequence Summary Report



SEA
OK 2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CODS\Projects\ADAD 2025\October 2025\Results\VMA
Methisopronol091025_VMA_Methisopronol_Kadar_MoA.usrl\LINERTAS 7538P1-
CZscientist.d

Sample name:

LINERTAS 75

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-10 23:41:47+07:00

Acq. operator:

scientist

Acq. method:

Methisopronol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisopronol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length:

150.0 mm

Location:

P1-C2

Column Diameter:

4.6 mm

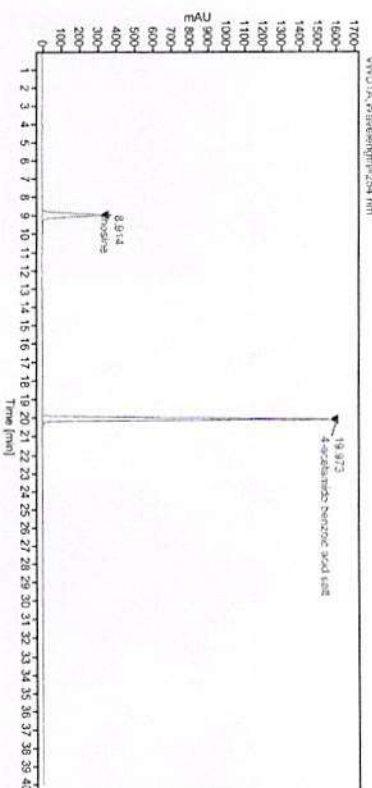
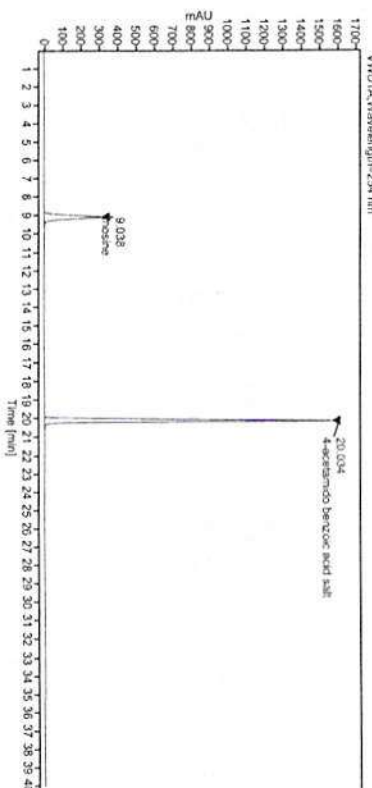
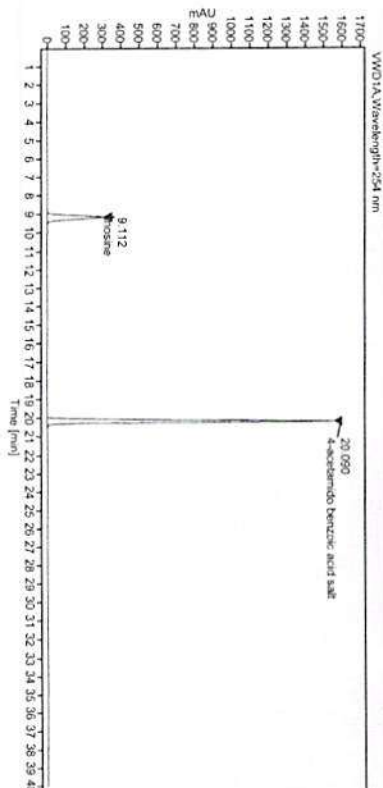
Name: 4-acetamido benzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 75	20.1	1554.6	13993.0628	36.6	1.02958	10/10/2025 23:41:47
LINERTAS 75	20.0	1568.1	13986.3777	37.1	1.02373	10/11/2025 00:23:05
LINERTAS 75	20.0	1567.0	13995.7271	37.3	1.01751	10/11/2025 01:04:24
		Mean	13991.7225			
		Std Dev.	4.8166			
		%RSD	0.0344			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 75	9.1	308.5	4188.8382		1.05180	10/10/2025 23:41:47
LINERTAS 75	9.0	312.6	4187.4344		1.05266	10/11/2025 00:23:05
LINERTAS 75	8.9	312.7	4182.0382		1.05072	10/11/2025 01:04:24
		Mean	4186.1036			
		Std Dev.	3.5900			
		%RSD	0.0858			



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file: E:\CDSP\Projects\AD\AD_2025\October 2025\Results\VMA_Methisopropinol_Kadar_MoA.rsl\LINIERITAS 10041P1-C3scientist.qxd

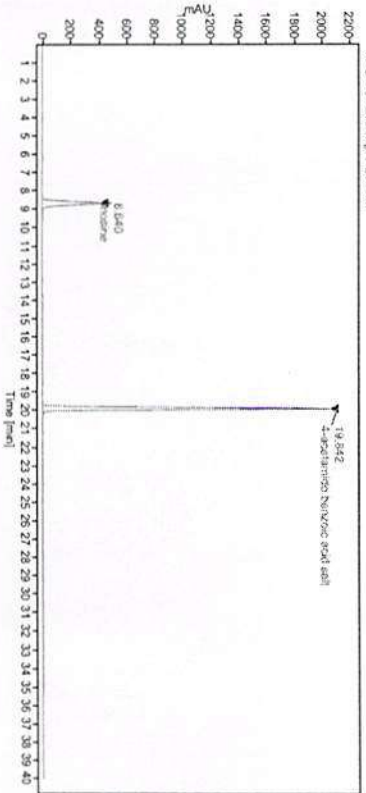
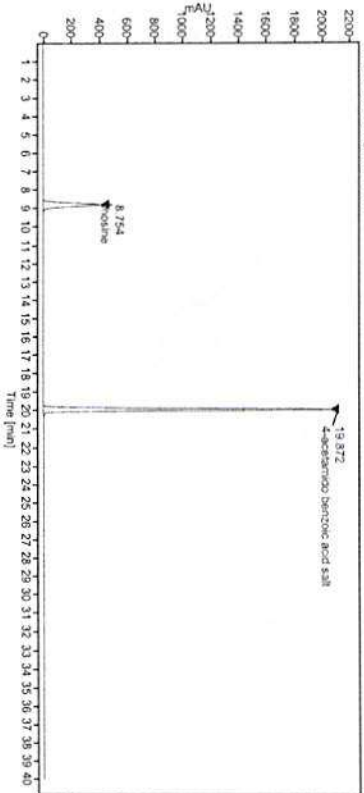
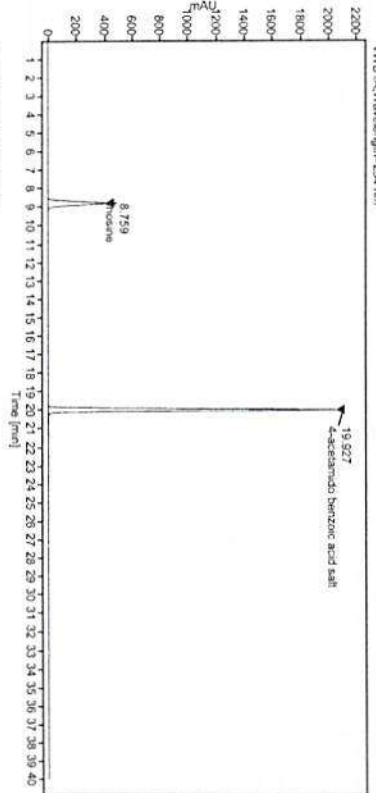
Sample name: LINIERITAS 100
 Instrument: LC 1260 UV
 Injection date: 2025-10-11 01:45:44+07:00
 Acq. method: Methisopropinol_Kadar_MoA.amx
 Analysis method: PM_VMA
 Methisopropinol_MoA.pmx
 Last changed: 2025-10-17 19:09:45+07:00
 Location: P1-C3
 Injection: 1 of 1
 Injection volume: 20.000
 Acq. operator: scientist
 Column name: Purophare RP 18 Endcapped (K53)
 Column Serial No: 310767
 Column Length: 150.0 mm
 Column Diameter: 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINIERITAS 100	19.9	2052.8	18437.4028	37.4	1.01473	10/11/2025 01:45:44
LINIERITAS 100	19.9	2056.7	18434.6121	37.4	1.01857	10/11/2025 02:27:03
LINIERITAS 100	19.8	2061.8	18423.6645	37.4	1.03033	10/11/2025 03:08:22
		Mean	18431.8931			
		Std Dev.	7.2615			
		%RSD	0.0394			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINIERITAS 100	8.8	412.9	5563.2206		1.06680	10/11/2025 01:45:44
LINIERITAS 100	8.8	413.8	5563.9495		1.06602	10/11/2025 02:27:03
LINIERITAS 100	8.6	409.4	5567.3919		1.05397	10/11/2025 03:08:22
		Mean	5564.8540			
		Std Dev.	2.2279			
		%RSD	0.0400			



SKA
 12-04-2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file: E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA_Methisopropinol_091025_VMA_Methisopropinol_Kadar_MoA.rsh\LINERTAS 1254AP1-C4scientist.d

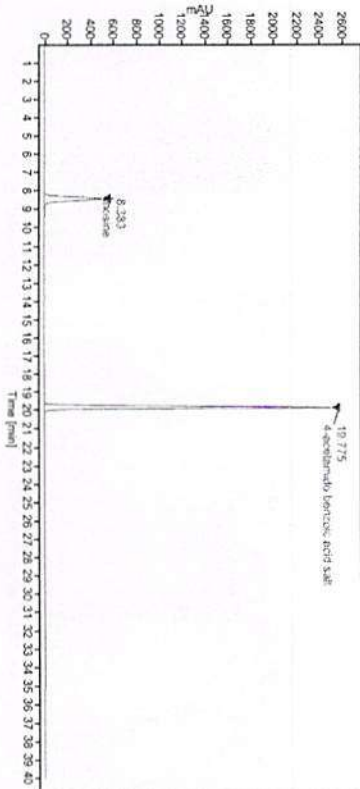
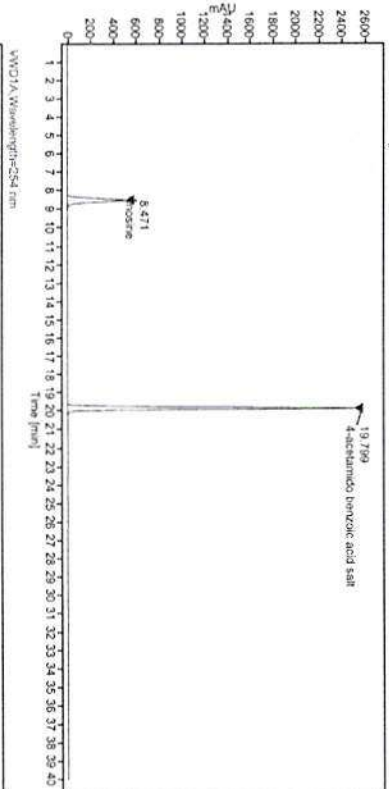
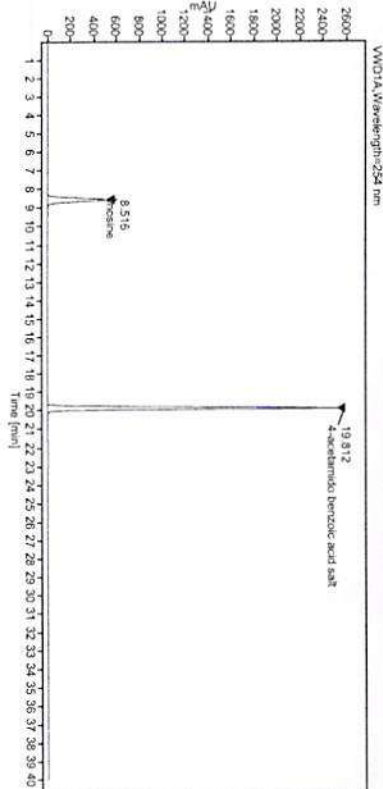
Sample name: LINERTAS 125
 Instrument: LC 1260 UV
 Injection date: 2025-10-11 03:43:41-07:00
 Acq. method: Methisopropinol_Kadar_MoA.amx
 Analysis method: *PM_VMA
 Methisopropinol_MoA.pmx
 Last changed: 2025-10-17 19:09:45-07:00
 Location: P1-C4
 Injection: 1 of 1
 Injection volume: 20.000
 Acq. operator: scientist
 Column name: Purosphere RP 18
 Endcapped (K53)
 Column Serial No: 310767
 Column Length: 150.0 mm
 Column Diameter: 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 125	19.8	2519.1	22782.4779	37.6	1.02452	10/11/2025 03:49:41
LINERTAS 125	19.8	2510.9	22817.3590	37.4	1.02498	10/11/2025 04:31:02
LINERTAS 125	19.8	2514.4	22796.7886	37.4	1.02809	10/11/2025 05:12:21
		Mean	22798.8752			
		Std Dev.	17.5339			
		%RSD	0.0769			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERTAS 125	8.5	512.5	6986.2981		1.07028	10/11/2025 03:49:41
LINERTAS 125	8.5	508.7	6991.1170		1.06723	10/11/2025 04:31:02
LINERTAS 125	8.4	502.8	6990.9951		1.06235	10/11/2025 05:12:21
		Mean	6989.4700			
		Std Dev.	2.7477			
		%RSD	0.0393			



SKA
19 OK 2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA
Methisoprolol_091025_VMA_Methisoprolol_Kadar_MoA.rst\LINERITAS 15047P1-
C5scientist.d

Sample name:

LINERITAS 150

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-11 05:53:43-07:00

Acq. operator:

scientist

Acq. method:

Methisoprolol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisoprolol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45-07:00

Column Length:

150.0 mm

Location:

P1-C5

Column Diameter:

4.6 mm

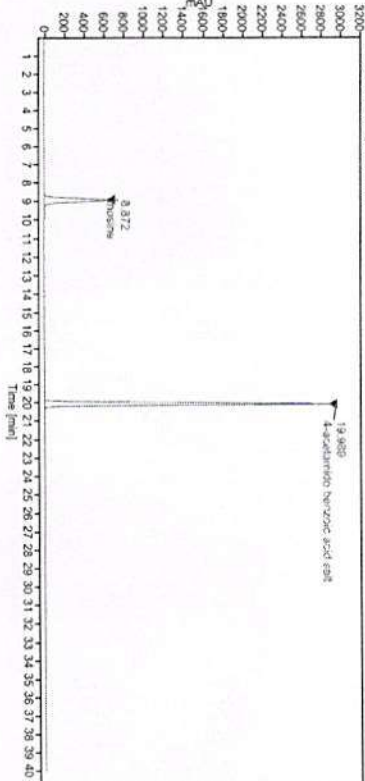
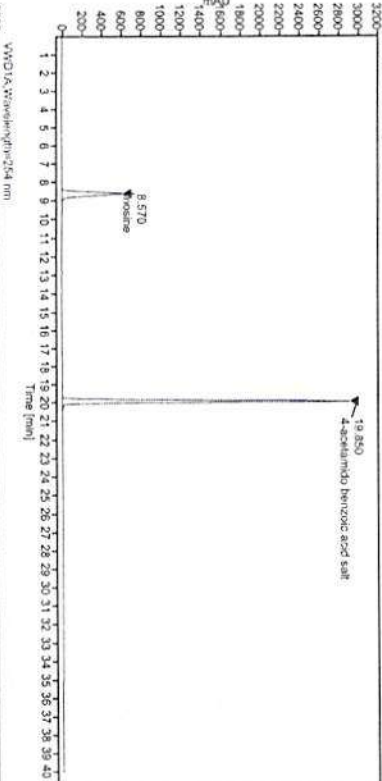
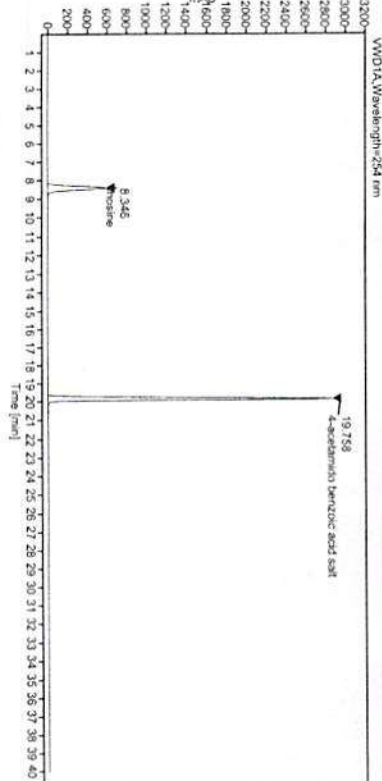
Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERITAS 150	19.8	2868.7	28670.1942	36.9	1.00920	10/11/2025 05:53:43
LINERITAS 150	19.9	2911.2	28589.8407	37.7	1.02031	10/11/2025 06:35:02
LINERITAS 150	20.0	2874.8	28575.3512	37.2	1.02772	10/11/2025 07:16:22
		Mean	28611.7954			
		Std Dev.	51.0911			
		%RSD	0.1920			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
LINERITAS 150	8.3	591.3	8350.8053		1.07189	10/11/2025 05:53:43
LINERITAS 150	8.6	618.2	8369.1084		1.07559	10/11/2025 06:35:02
LINERITAS 150	8.9	627.1	8381.5826		1.07455	10/11/2025 07:16:22
		Mean	8367.1654			
		Std Dev.	15.4804			
		%RSD	0.1850			



5/14
12-05-2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file: E:\CDSP\Projects\ADIAD_2025\October 2025\Results\VMA_Methisoprinol_091025_VMA_Methisoprinol_Kadar_MoA.rsl\AKURASI 8020P1-Btscientist.d

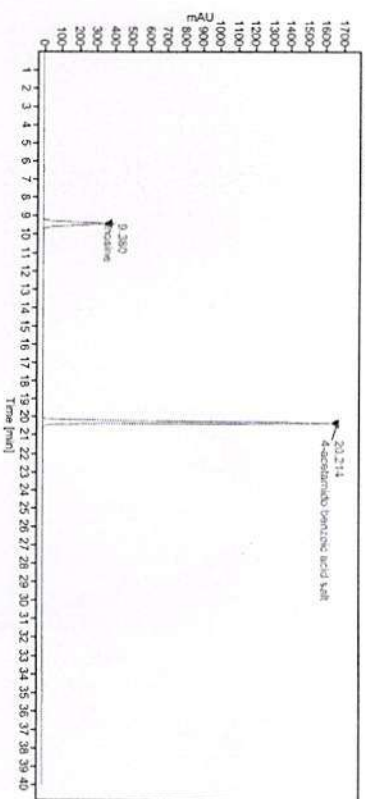
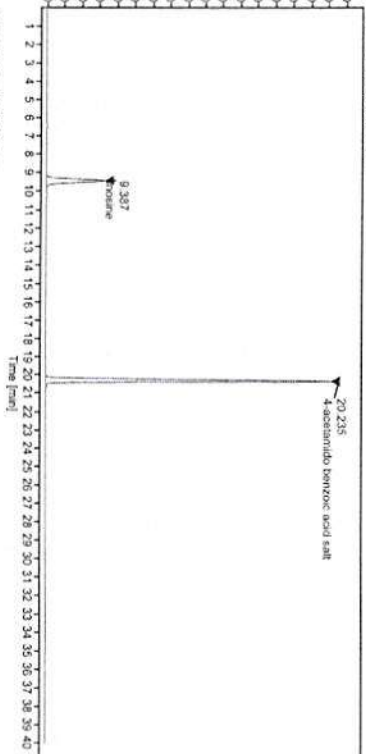
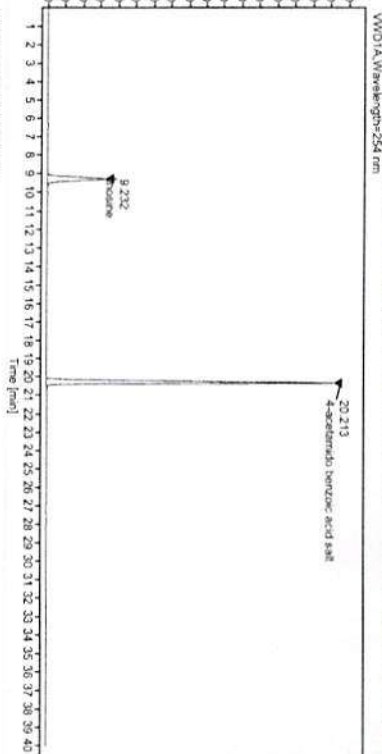
Sample name: AKURASI 80
 Instrument: LC 1260 UV
 Injection date: 2025-10-10 11:18:20+07:00
 Acq. method: Methisoprinol_Kadar_MoA.amx
 Analysis method: PM_VMA
 Methisoprinol_MoA.pmx
 Last changed: 2025-10-17 19:09:45+07:00
 Location: P1-81
 Injection: 1 of 1
 Injection volume: 20.000
 Acq. operator: scientist
 Column name: Purosphere RP 18
 Endcapped (K53)
 Column Serial No: 310767
 Column Length: 150.0 mm
 Column Diameter: 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 80	20.2	1622.2	14642.5035	36.9	1.02676	10/10/2025 11:18:20
AKURASI 80	20.2	1623.3	14634.7880	36.7	1.02939	10/10/2025 11:59:39
AKURASI 80	20.2	1631.9	14638.7845	37.0	1.03437	10/10/2025 12:40:59
		Mean	14638.6920			
		Std Dev.	3.8586			
		%RSD	0.0264			

Name: Ilosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 80	9.2	330.6	4399.1170		1.06797	10/10/2025 11:18:20
AKURASI 80	9.4	333.6	4407.0323		1.07173	10/10/2025 11:59:39
AKURASI 80	9.4	338.0	4406.4209		1.06174	10/10/2025 12:40:59
		Mean	4404.1901			
		Std Dev.	4.4041			
		%RSD	0.1000			



SKA
 17 OKT 2025

Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA_Methisopropinol_091025_VMA_Methisopropinol_Kadar_MoA.sft\AKURASI 10025P1-B4.scientist.d

Sample name:

AKURASI 100

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-10 14:44:53+07:00

Acq. operator:

scientist

Acq. method:

Methisopropinol_Kadar_MoA.amx

Column name:

Purosphare RP 18 Endcapped (K53)

Analysis method:

*RM_VMA
Methisopropinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-B4

Column Diameter :

4.6 mm

Name: 4-acetamidobenzoic acid salt

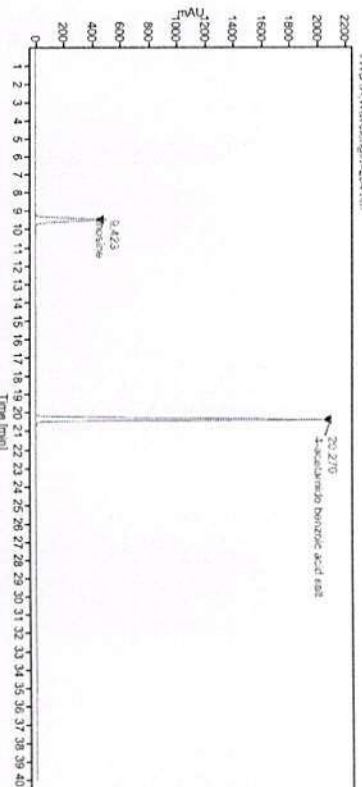
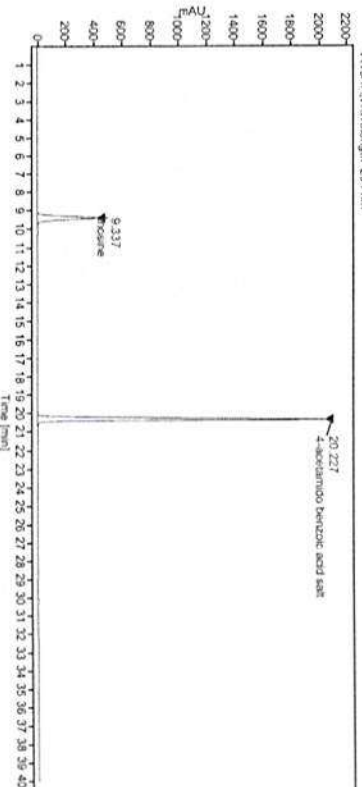
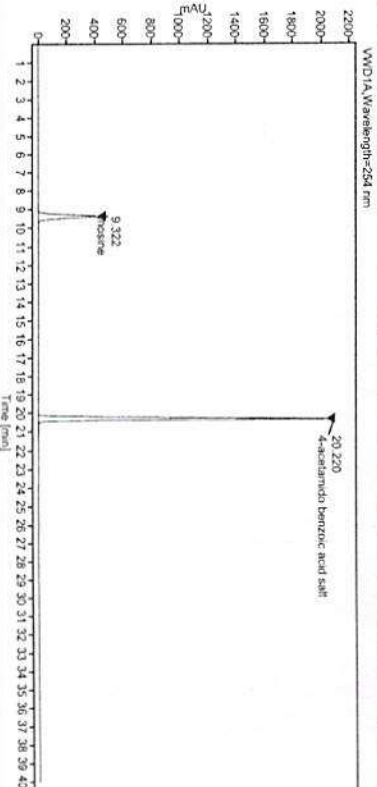
Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 100	20.2	2040.3	18339.3375	37.1	1.03782	10/10/2025 14:44:53
AKURASI 100	20.2	2045.1	18345.5211	37.2	1.03102	10/10/2025 15:26:10
AKURASI 100	20.3	2041.9	18346.0538	37.0	1.03059	10/10/2025 16:07:29
		Mean	18343.6375			
		Std Dev.	3.7334			
		%RSD	0.0204			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 100	9.3	420.2	5513.2802		1.06853	10/10/2025 14:44:53
AKURASI 100	9.3	423.0	5515.6945		1.06658	10/10/2025 15:26:10
AKURASI 100	9.4	422.6	5515.4987		1.06176	10/10/2025 16:07:29
		Mean	5514.8245			
		Std Dev.	1.3409			
		%RSD	0.0243			

Cross Sequence Summary Report



SKA
17/10/2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA
Methisoprinol\091025_VMA_Methisoprinol Kadar_MoA.rsl\AKURASI 10028P1-
BScientist.d

Sample name: AKURASI 100
Instrument: LC 1260 UV
Injection date: 2025-10-10 16:48:48+07:00
Acq. method: Methisoprinol_Kadar_MoA.amx
Analysis method: *PM_VMA
Methisoprinol_MoA.pmx
Last changed: 2025-10-17 19:09:45+07:00
Location: P1-B6

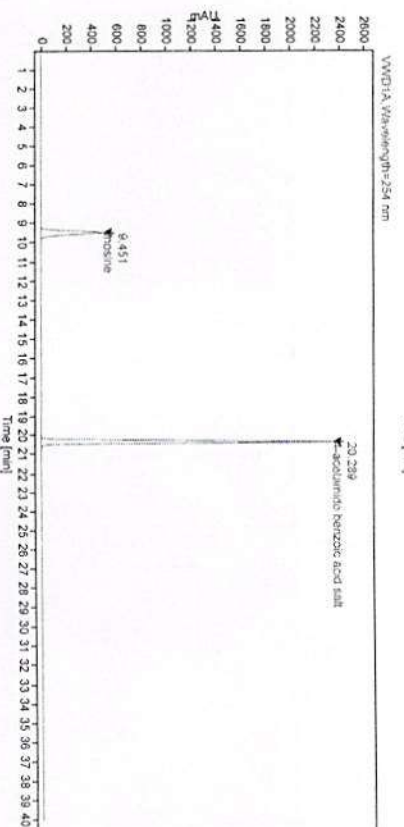
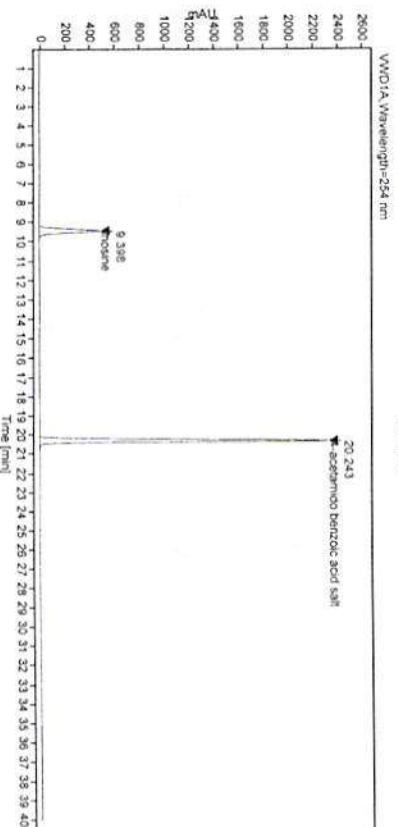
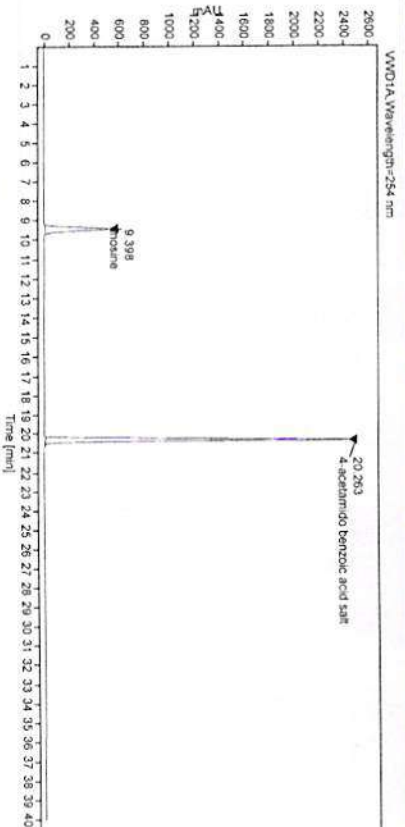
Injection: 1 of 1
Injection volume: 20.000
Acq. operator: scientist
Column name: Purosphere RP 18
Endcapped (K53)
Column Serial No: 310767
Column Length: 150.0 mm
Column Diameter: 4.6 mm

Name: 4-acetamido benzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 120	20.3	2431.4	21917.5509	37.1	1.03304	10/10/2025 16:48:48
AKURASI 120	20.2	2338.2	21302.3911	36.5	1.02624	10/10/2025 17:30:08
AKURASI 120	20.3	2347.0	21399.7007	36.7	1.01955	10/10/2025 18:11:26
		Mean	21539.8809			
		Std Dev	330.6709			
		%RSD	1.5352			

Name:

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
AKURASI 120	9.4	519.2	6599.2448		1.05994	10/10/2025 16:48:48
AKURASI 120	9.4	495.7	6554.9459		1.07379	10/10/2025 17:30:08
AKURASI 120	9.5	500.2	6594.0174		1.06947	10/10/2025 18:11:26
		Mean	6582.7360			
		Std Dev	24.2085			
		%RSD	0.3678			



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADIAD 2025\October 2025\Results\VMA
Methisopronol_091025_VMA_Methisopronol_Kadar_MoA.rsl\PRESISI ANTARA
151P1-D1\scientist.tlx

Sample name:

PRESISI ANTARA 1

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-11 08:38:58+07:00

Acq. operator:

scientist

Acq. method:

Methisopronol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (KSS)

Analysis method:

PM_VMA
Methisopronol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-D1

Column Diameter :

4.6 mm

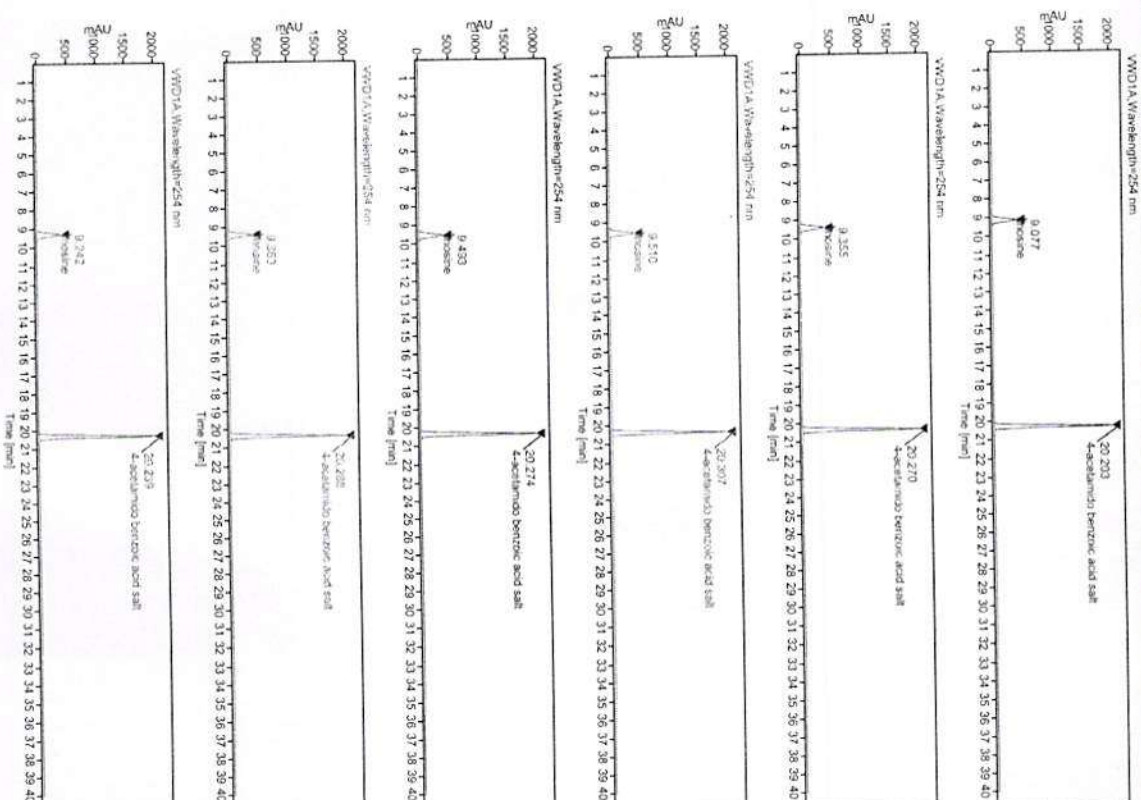
Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
PRESISI ANTARA 1	20.2	2001.2	18249.3688	36.6	1.04100	10/11/2025 08:38:58
PRESISI ANTARA 1	20.3	1968.1	18237.0472	35.8	1.03719	10/11/2025 09:20:16
PRESISI ANTARA 1	20.3	1971.4	18270.4371	35.8	1.04818	10/11/2025 10:01:26
PRESISI ANTARA 1	20.3	1973.8	18287.9404	35.6	1.04532	10/11/2025 10:42:56
PRESISI ANTARA 1	20.3	1974.1	18312.8727	35.9	1.03302	10/11/2025 11:24:17
PRESISI ANTARA 1	20.2	1966.7	18196.6402	36.2	1.02784	10/11/2025 12:05:36
		Mean	18259.0511			
		Std Dev.	40.8265			
		%RSD	0.2236			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
PRESISI ANTARA 1	9.1	403.2	5528.5972		1.07716	10/11/2025 08:38:58
PRESISI ANTARA 1	9.4	401.7	5520.6737		1.07810	10/11/2025 09:20:16
PRESISI ANTARA 1	9.5	412.6	5523.3404		1.07712	10/11/2025 10:01:36
PRESISI ANTARA 1	9.5	411.3	5537.7232		1.07203	10/11/2025 10:42:56
PRESISI ANTARA 1	9.4	406.8	5533.7474		1.07802	10/11/2025 11:24:17
PRESISI ANTARA 1	9.2	407.2	5515.5573		1.08301	10/11/2025 12:05:36
		Mean	5526.9199			
		Std Dev.	8.7098			
		%RSD	0.1576			

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\projects\ADAD 2025\October 2025\Results\VMA_Methisopronolol025_VMA_Methisopronolol Kadar_MoA.rsl\STANDARD 0 JAM8P1-E1\scientistdx

Sample name:

STANDARD 0 JAM

Injection: 1 of 1

Instrument:

LC 1260 UV

Injection volume: 20.000

Injection date:

2025-10-12 04:35:30+07:00

Acq. operator: scientist

Acq. method:

Methisopronolol_Kadar_MoA.amx

Column name:

Purosphere RP 18 Endcapped (K53)

Analysis method:

*PM_VMA_Methisopronolol_MoA.pmx

Column Serial No 310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length: 150.0 mm

Location:

P1-E1

Column Diameter: 4.6 mm

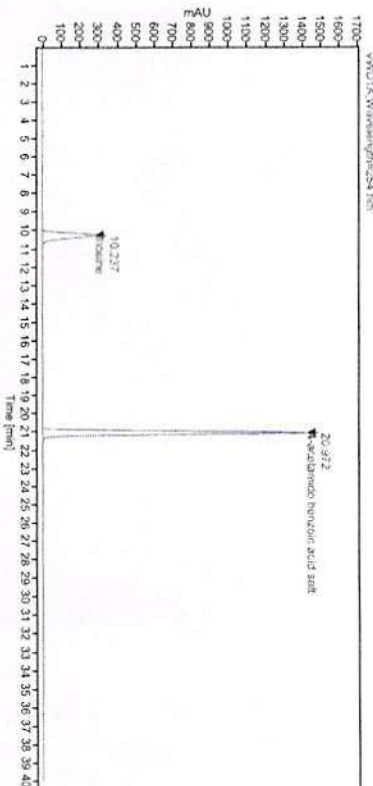
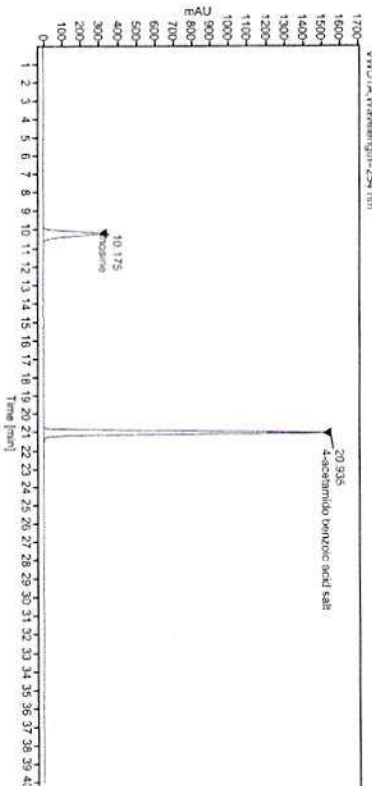
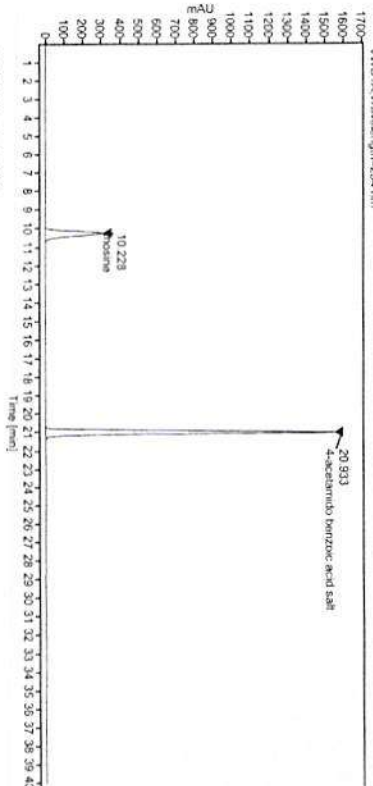
Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 0 JAM	20.9	1551.8	18461.9368	27.2	1.18607	10/12/2025 04:35:30
STANDARD 0 JAM	20.9	1505.9	18473.2832	26.4	1.21273	10/12/2025 05:16:48
STANDARD 0 JAM	21.0	1424.1	18484.2374	24.8	1.26132	10/12/2025 06:39:22
		Mean	18473.1524			
		Std Dev.	11.1509			
		%RSD	0.0604			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 0 JAM	10.2	310.2	5515.6520		1.18216	10/12/2025 04:35:30
STANDARD 0 JAM	10.2	298.6	5514.0963		1.21750	10/12/2025 05:16:48
STANDARD 0 JAM	10.2	283.7	5513.8244		1.28434	10/12/2025 06:39:22
		Mean	5514.5242			
		Std Dev.	0.9861			
		%RSD	0.0179			

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA
Methisopron\091025_VMA_Methisopron\Kadar_MoA.rsl\STANDARD 3
JAM87P1-E1\scientist.dx

Sample name:

STANDARD 3 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-12 07:40:54+07:00

Acq. operator:

scientist

Acq. method:

Methisopron_Kadar_MoA.amx

Column name:

Purosphare RP 18
Endcapped (K53)

Analysis method:

*PM_VMA
Methisopron_L_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E1

Column Diameter :

4.6 mm

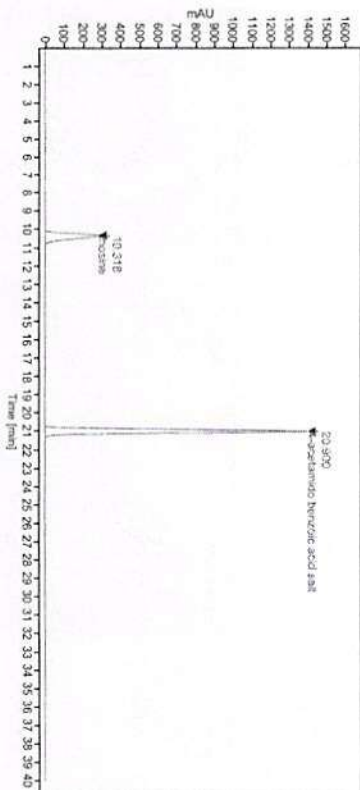
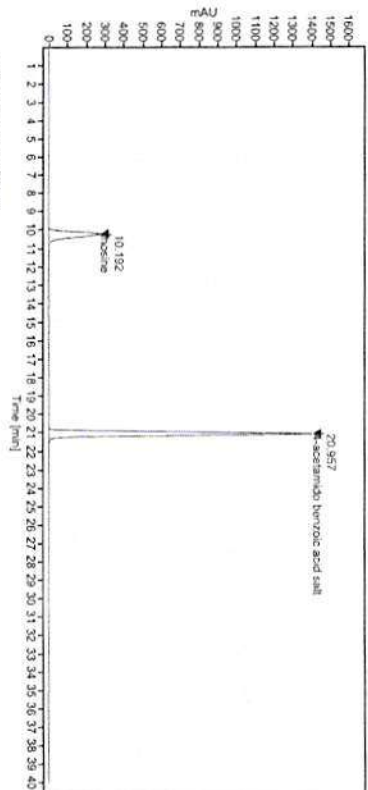
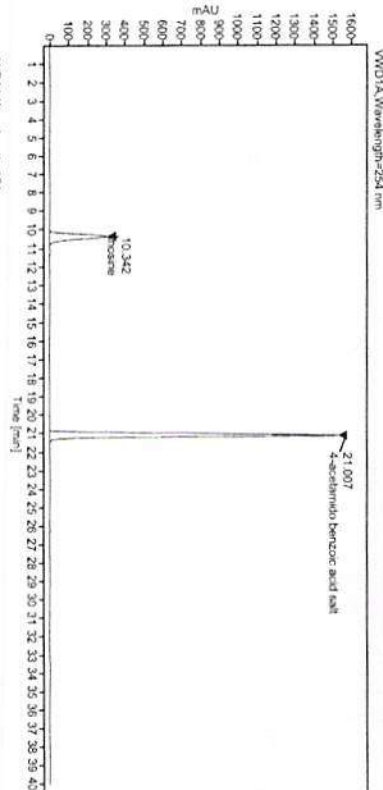
Name: 4-acetamido benzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 3 JAM	21.0	1529.9	18425.5220	26.9	1.16669	10/12/2025 07:40:54
STANDARD 3 JAM	21.0	1404.6	18505.9330	24.2	1.26589	10/12/2025 08:22:11
STANDARD 3 JAM	20.9	1396.0	18535.4271	24.0	1.32189	10/12/2025 09:03:29
		Mean	18488.9607			
		Std Dev.	56.8843			
		%RSD	0.3077			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 3 JAM	10.3	308.0	5506.0427		1.16915	10/12/2025 07:40:54
STANDARD 3 JAM	10.2	274.3	5508.7485		1.32948	10/12/2025 08:22:11
STANDARD 3 JAM	10.3	280.9	5510.3326		1.33925	10/12/2025 09:03:29
		Mean	5508.3746			
		Std Dev.	2.1692			
		%RSD	0.0394			

Cross Sequence Summary Report



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Project\ADAD 2025\October 2025\Results\VMA_Methisopronolol_91025_VMA_Methisopronolol_Kadar_MoA.rsl\STANDARD 6 JAM\92P1-E1\scientist1.d

Sample name: STANDARD 6 JAM

Injection: 1 of 1

Instrument: LC 1260 UV

Injection volume: 20.000

Injection date: 2025-10-12 10:46:13+07:00

Acq. operator: scientist

Acq. method: Methisopronolol_Kadar_MoA.amx

Column name: Purosphere RP 18 Endcapped (K53)

Analysis method: PMA_VMA_Methisopronolol_MoA.pmx

Column Serial No: 310767

Last changed: 2025-10-17 19:09:45+07:00

Column Length: 150.0 mm

Location: P1-E1

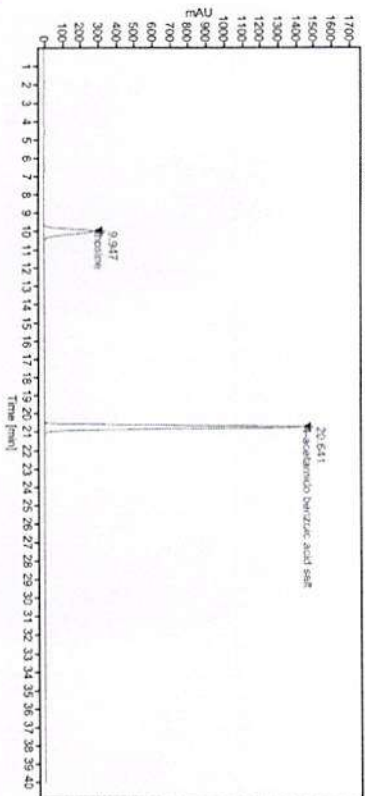
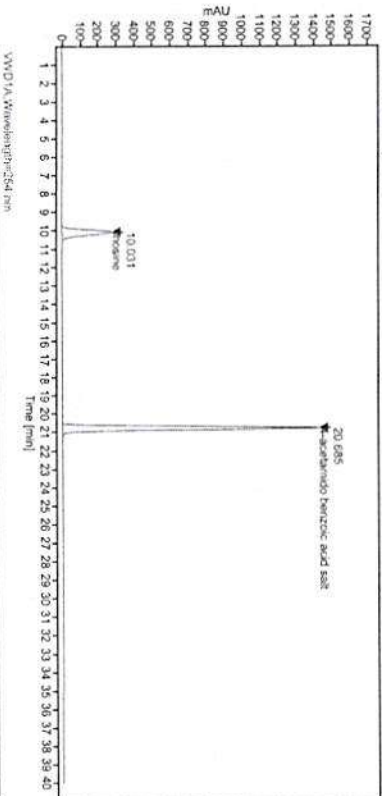
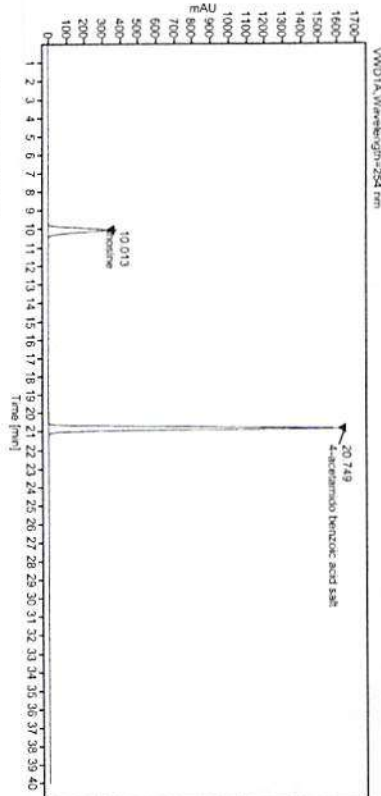
Column Diameter: 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 6 JAM	20.7	1602.4	18499.9874	28.3	1.19655	10/12/2025 10:46:13
STANDARD 6 JAM	20.7	1431.2	18576.0795	24.3	1.28548	10/12/2025 11:27:31
STANDARD 6 JAM	20.6	1434.1	18585.3000	24.3	1.29826	10/12/2025 12:08:49
		Mean	18553.7890			
		Std Dev.	46.8211			
		%RSD	0.2524			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 6 JAM	10.0	322.3	5507.3649		1.18934	10/12/2025 10:46:13
STANDARD 6 JAM	10.0	279.5	5515.0930		1.29307	10/12/2025 11:27:31
STANDARD 6 JAM	9.9	276.6	5522.9970		1.30402	10/12/2025 12:08:49
		Mean	5515.1517			
		Std Dev.	7.8162			
		%RSD	0.1417			



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA
Methisoprinol091025_VMA_Methisoprinol_Kadar_Moa.rsl\STANDARD 9
JAM97P1-E1\scientist.d\

Sample name:

STANDARD 9 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-12 13:51:35+07:00

Acq. operator:

scientist

Acq. method:

Methisoprinol_Kadar_Moa.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisoprinol_Moa.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E1

Column Diameter :

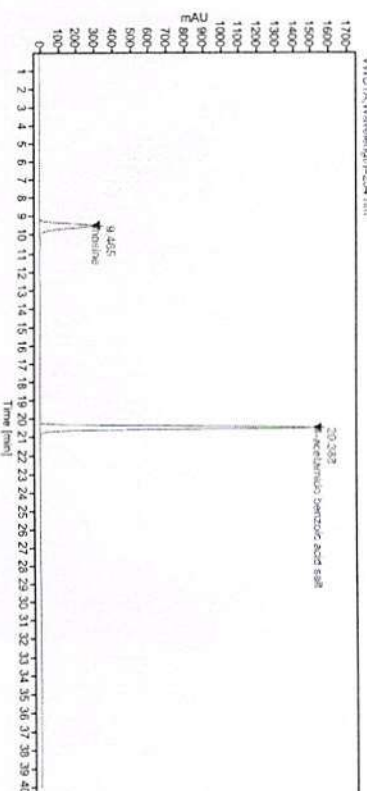
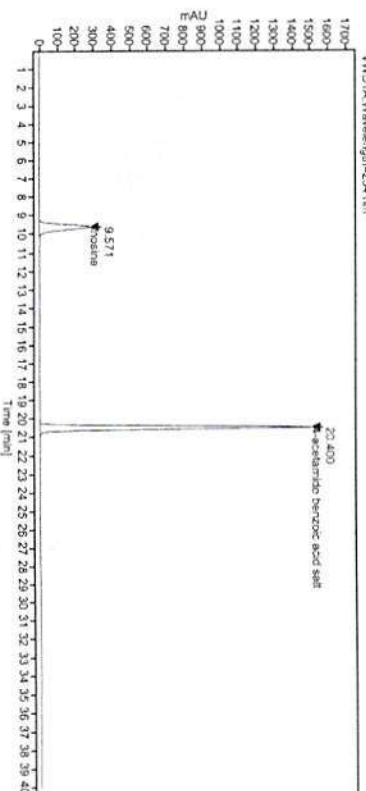
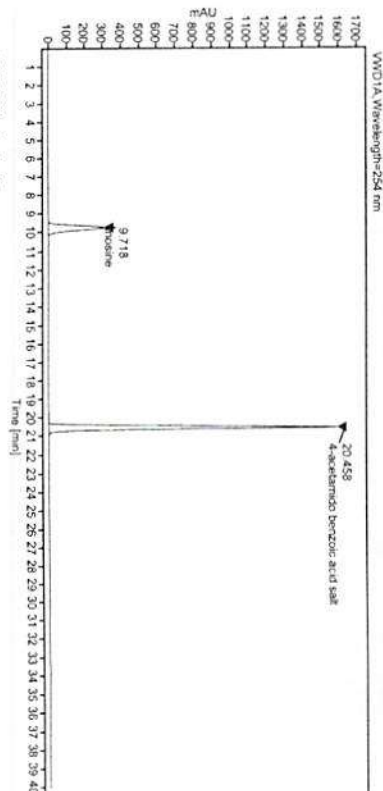
4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 9 JAM	20.5	1595.1	18570.0120	27.7	1.20396	10/12/2025 13:51:35
STANDARD 9 JAM	20.4	1507.4	18617.9411	25.5	1.21413	10/12/2025 14:32:53
STANDARD 9 JAM	20.4	1512.6	18619.1136	26.0	1.21910	10/12/2025 15:14:11
		Mean	18602.3556			
		Std Dev:	28.0165			
		%RSD	0.1506			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 9 JAM	9.7	313.3	5520.6853		1.19856	10/12/2025 13:51:35
STANDARD 9 JAM	9.6	281.5	5531.4588		1.24124	10/12/2025 14:32:53
STANDARD 9 JAM	9.5	285.1	5532.7123		1.23001	10/12/2025 15:14:11
		Mean	5528.2855			
		Std Dev:	6.6117			
		%RSD	0.1196			



Handwritten signature and date: 12-OKT-2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\ODSProjects\AD\AD 2025\October 2025\Results\VMA
Methisoprinol_091025_VMA_Methisoprinol_Kadar_MoA.rst\STANDARD 12
JAM106P1-E1scientist.dx

Sample name:

STANDARD 12 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-12 19:42:19+07:00

Acq. operator:

scientist

Acq. method:

Methisoprinol_Kadar_MoA.rmx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisoprinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E1

Column Diameter :

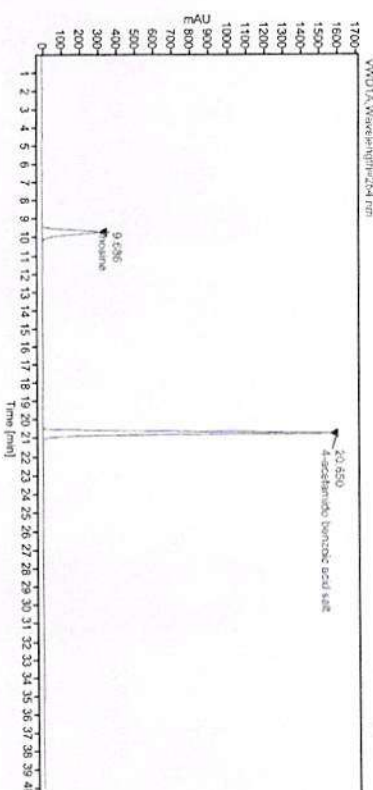
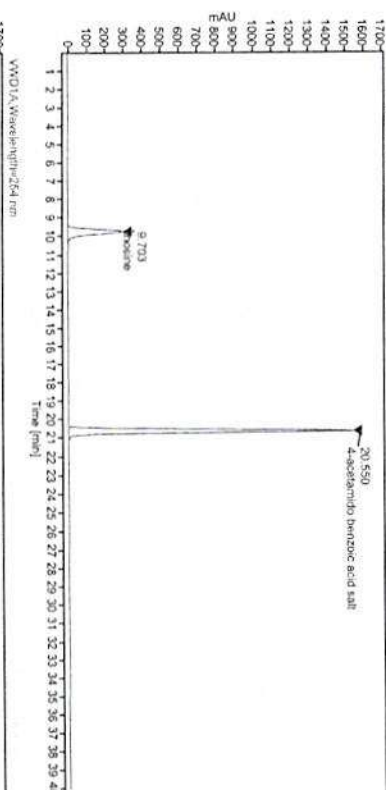
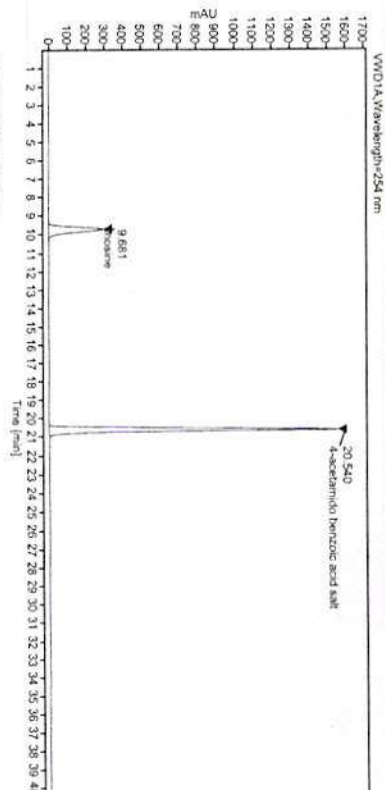
4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 12 JAM	20.5	1561.3	18578.5777	27.2	1.23118	10/12/2025 19:42:19
STANDARD 12 JAM	20.6	1546.1	18567.4911	27.2	1.23862	10/12/2025 20:23:36
STANDARD 12 JAM	20.6	1557.6	18556.4434	27.8	1.23507	10/12/2025 21:04:56
		Mean	18567.5041			
		Std Dev.	11.0672			
		%RSD	0.0596			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 12 JAM	9.7	298.7	5539.2477		1.24050	10/12/2025 19:42:19
STANDARD 12 JAM	9.7	300.2	5536.1051		1.23100	10/12/2025 20:23:36
STANDARD 12 JAM	9.7	302.7	5534.1242		1.24757	10/12/2025 21:04:56
		Mean	5536.4923			
		Std Dev.	2.5636			
		%RSD	0.0467			



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\Oktobar 2025\Results\VMA
Metisopropinol\091025_VMA_Metisopropinol_Kadar_MoA.rst\1STANDARD 24
JAM121P1-E1scientist1dx

Sample name: STANDARD 24 JAM

Injection: 1 of 1

Instrument: LC 1260 UV

Injection volume: 20.000

Injection date: 2025-10-13 07:10:27+07:00

Acq. operator: scientist

Acq. method: Metisopropinol_Kadar_MoA.anx

Column name: Purosphate RP 18
Endcapped (K5)Analysis method: *PM VMA
Metisopropinol_MoA.pmxColumn Serial No
310767

Last changed: 2025-10-17 19:09:45+07:00

Column Length : 150.0 mm

Location: P1-E1

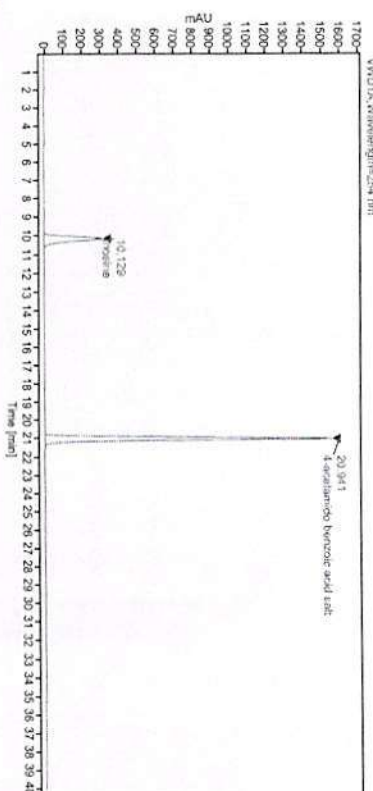
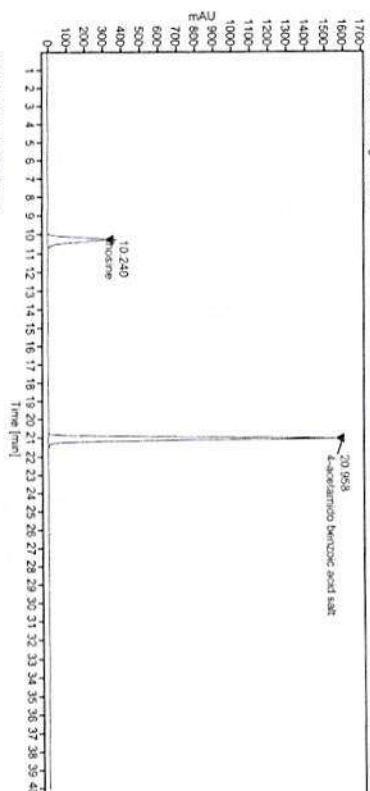
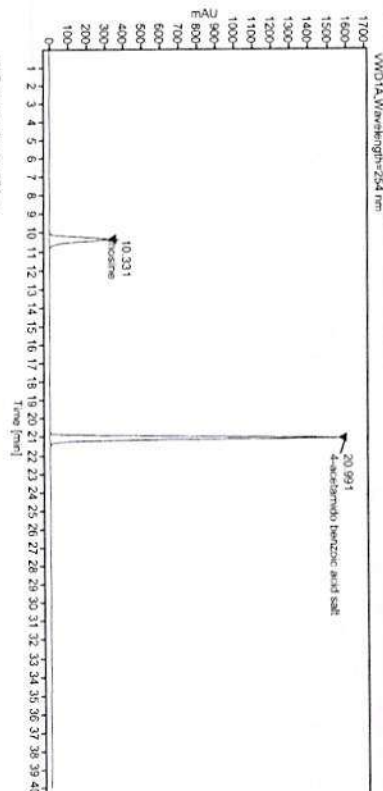
Column Diameter : 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 24 JAM	21.0	1559.2	18459.5461	27.9	1.20434	10/13/2025 07:10:27
STANDARD 24 JAM	21.0	1561.1	18472.3369	27.8	1.23020	10/13/2025 07:51:44
STANDARD 24 JAM	20.9	1563.1	18473.4162	28.2	1.23617	10/13/2025 08:33:02
		Mean	18468.4331			
		Std Dev.	7.7152			
		%RSD	0.0418			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
STANDARD 24 JAM	10.3	315.7	5502.1338		1.20156	10/13/2025 07:10:27
STANDARD 24 JAM	10.2	311.8	5508.8619		1.21601	10/13/2025 07:51:44
STANDARD 24 JAM	10.1	314.8	5508.4596		1.22326	10/13/2025 08:33:02
		Mean	5506.4851			
		Std Dev.	3.7737			
		%RSD	0.0685			



SKA
10.10.2025

Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Projects\ADAD 2025\October 2025\Results\VMA
Methisoprinolol091025_VMA_Methisoprinolol Kadar_MoA.rst\SAMPLEL 0 JAM59P1-
E2scientist.qx

Sample name:

SAMPLEL 0 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-11 13:28:15-07:00

Acq. operator:

scientist

Acq. method:

Methisoprinolol_Kadar_MoA.amx

Column name:

Pursaphare RP 18
Endcapped (K53)

Analysis method:

*PM_VMA
Methisoprinolol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E2

Column Diameter :

4.6 mm

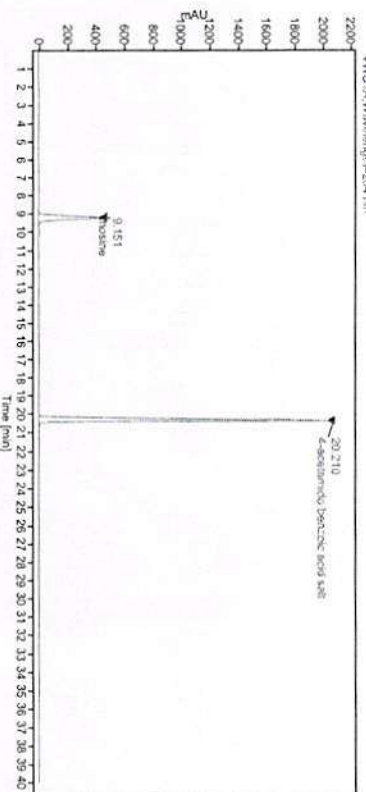
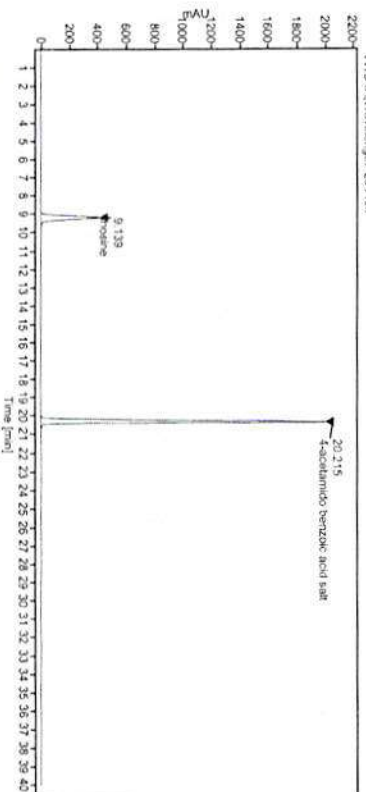
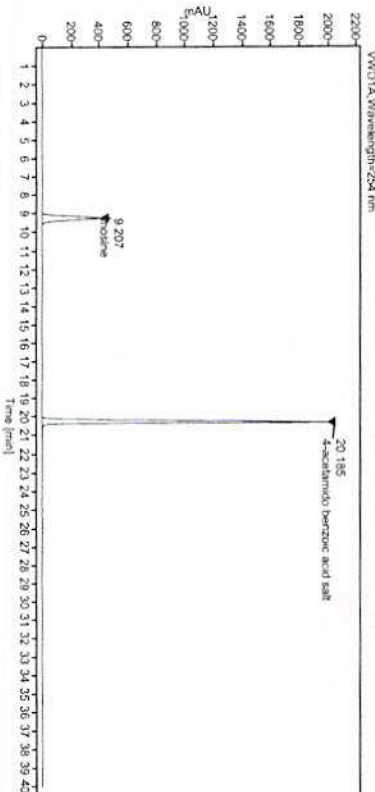
Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLEL 0 JAM	20.2	1894.7	18431.5469	35.7	1.04784	10/11/2025 13:28:15
SAMPLEL 0 JAM	20.2	2001.7	18422.4117	36.4	1.04806	10/11/2025 14:09:35
SAMPLEL 0 JAM	20.2	2025.1	18410.3396	36.7	1.02393	10/11/2025 14:50:56
		Mean	18421.4327			
		Std Dev.	10.6375			
		%RSD	0.0577			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLEL 0 JAM	9.2	407.4	5659.7009		1.06951	10/11/2025 13:28:15
SAMPLEL 0 JAM	9.1	412.7	5660.3946		1.06800	10/11/2025 14:09:35
SAMPLEL 0 JAM	9.2	417.9	5663.2492		1.06589	10/11/2025 14:50:56
		Mean	5661.1149			
		Std Dev.	1.8806			
		%RSD	0.0332			



Cross Sequence Summary Report



Data file:

E:\CDSP\jects\ADAD 2025\October 2025\Results\VMA
Methisopronol_091025_VMA_Methisopronol_Kadar_Moa.rsh\SAMPEL 3 JAM63P1-
E2scientist.qx

Sample name:

SAMPEL 3 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-11 16:33:47+07:00

Acq. operator:

scientist

Acq. method:

Methisopronol_Kadar_Moa.amx

Column name:

Purosphare RP 18
Endcapped (K53)

Analysis method:

¹H₁_VMA
Methisopronol_Moa.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E2

Column Diameter :

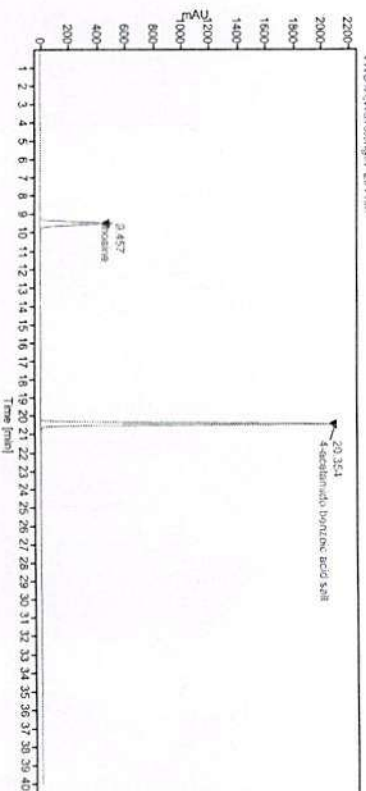
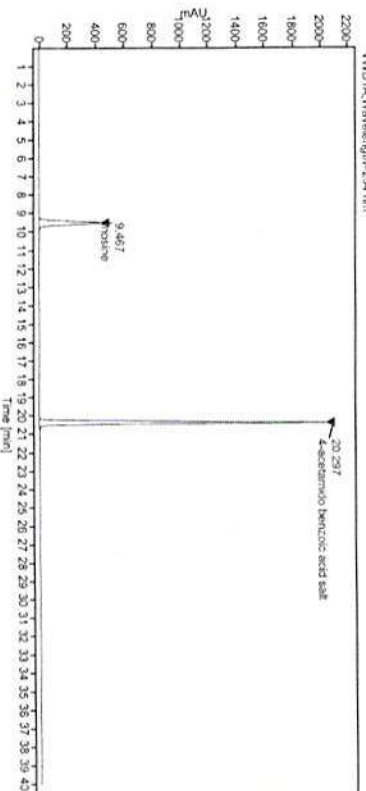
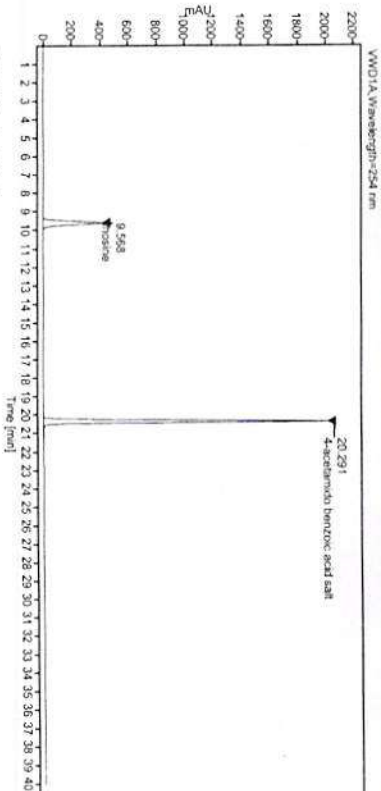
4.6 mm

Name: 4-acetamido benzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 3 JAM	20.3	2013.1	18398.5556	35.7	1.03711	10/11/2025 16:33:47
SAMPEL 3 JAM	20.3	2041.8	18376.1601	37.4	1.04478	10/11/2025 17:15:07
SAMPEL 3 JAM	20.4	2051.2	18376.0363	37.0	1.05068	10/11/2025 17:56:29
		Mean	18384.2507			
		Std Dev.	12.4339			
		%RSD	0.0676			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 3 JAM	9.6	420.3	5656.3189		1.07197	10/11/2025 16:33:47
SAMPEL 3 JAM	9.5	441.2	5663.7933		1.07150	10/11/2025 17:15:07
SAMPEL 3 JAM	9.5	430.8	5668.3813		1.06958	10/11/2025 17:56:29
		Mean	5662.8312			
		Std Dev.	6.0885			
		%RSD	0.1075			



Cross Sequence Summary Report



SKA
17-10-2025

Cross Sequence Summary Report



Data file:

E:\CDS\Projects\ADAD 2025\October 2025\Results\VMA
Methisoprinol_091025_VMA_Methisoprinol_Kadar_Moa.rsl(SAMPLE 6 JAM68P1-
Ezscientist.d)

Sample name:

SAMPLE 6 JAM

Instrument:

LC 1260 UV

Injection date:

2025-10-11 19:39:17+07:00

Acq. method:

Methisoprinol_Kadar_Moa.amx

Analysis method:

PM_VMA
Methisoprinol_Moa.pmx

Last changed:

2025-10-17 19:09:45+07:00

Location:

P1-E2

Injection:

1 of 1

Injection volume:

20.000

Acq. operator:

scientist

Column name:

Purosphere RP 18
Endcapped (K53)

Column Serial No

310767

Column Length:

150.0 mm

Column Diameter:

4.6 mm

Name:

4-acetamidobenzoic acid salt

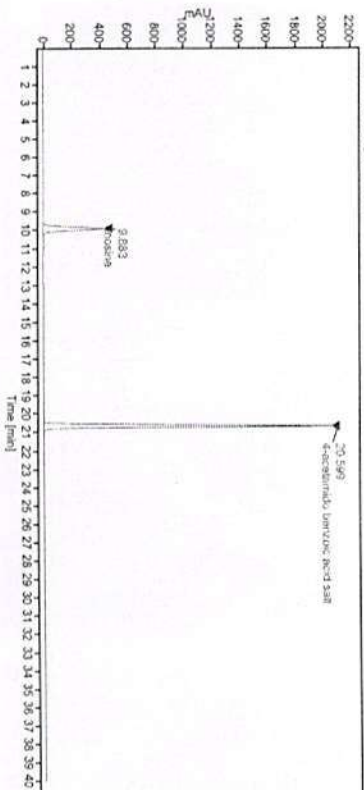
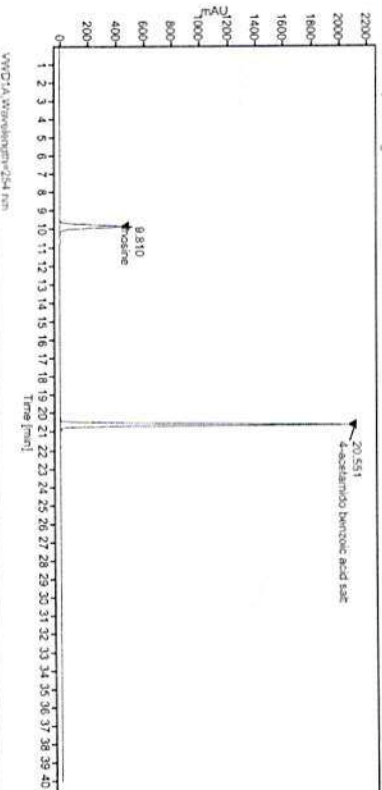
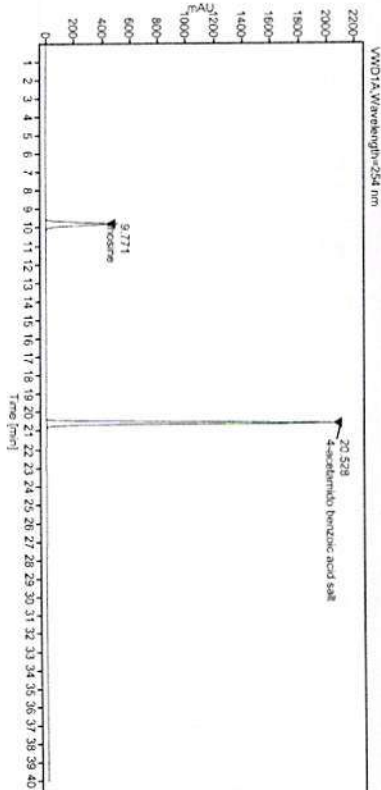
Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLE 6 JAM	20.5	2047.6	18347.6351	36.8	1.06302	10/11/2025 19:39:17
SAMPLE 6 JAM	20.6	2060.7	18315.2083	37.0	1.07433	10/11/2025 20:20:37
SAMPLE 6 JAM	20.6	2062.2	18308.1580	36.7	1.08504	10/11/2025 21:01:56
		Mean	18323.6671			
		Std Dev.	21.0541			
		%RSD	0.1149			

Name:

Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLE 6 JAM	9.8	435.0	5659.4607		1.07905	10/11/2025 19:39:17
SAMPLE 6 JAM	9.8	438.3	5664.4169		1.07980	10/11/2025 20:20:37
SAMPLE 6 JAM	9.9	433.7	5666.4144		1.07767	10/11/2025 21:01:56
		Mean	5663.4307			
		Std Dev.	3.5802			
		%RSD	0.0632			

Cross Sequence Summary Report



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file: E:\CDSProjects\AD\AD 2025\October 2025\Results\VA

Metisoprinol091025_VMA_Metisoprinol Kadar_MoA.rst\SAMPEL 9 JAN73P1-

EZscientist dx

Sample name: SAMPEL 9 JAM

Instrument: LC 1260 UV

Injection date: 2025-10-11 22:44:45+07:00

Acq. method: Metisoprinol_Kadar_MoA.amx

Analysis method: *PM VMA

Last changed: 2025-10-17 19:09:45+07:00

Location: P1-E2

Injection: 1 of 1

Injection volume: 20.000

Acq. operator: scientist

Column name: Puresphare RP 18

Column Serial No

Column Length : 150.0 mm

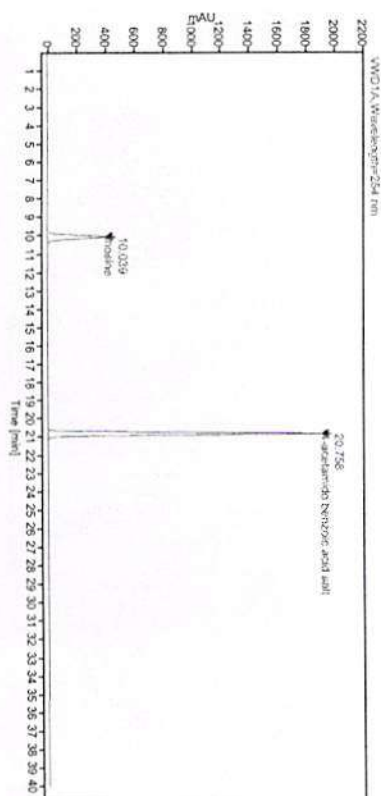
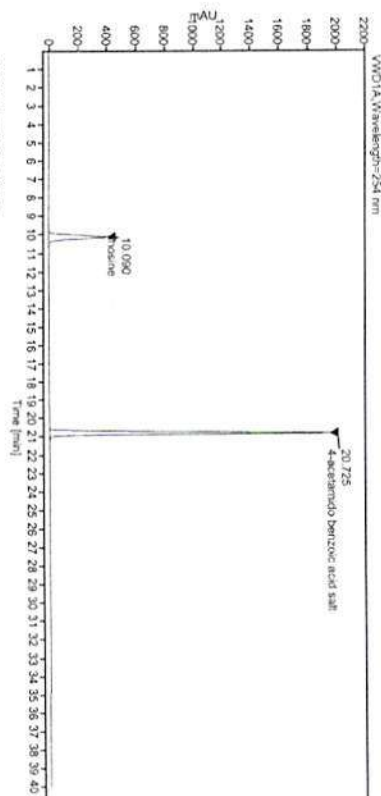
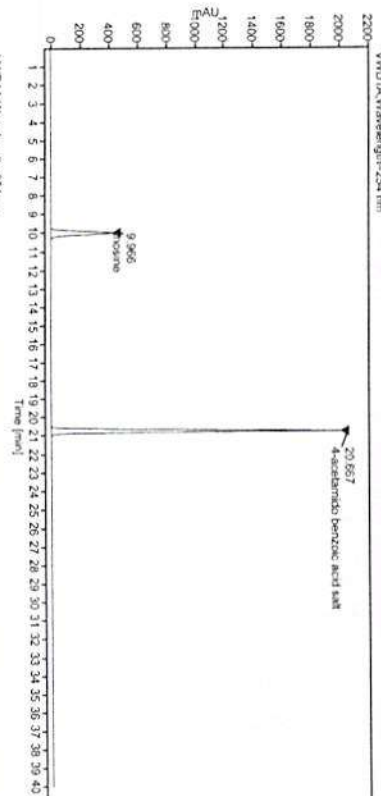
Column Diameter : 4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 9 JAM	20.7	2002.9	18337.0249	36.0	1.10762	10/11/2025 22:44:45
SAMPEL 9 JAM	20.7	1953.4	18372.5771	34.3	1.10660	10/11/2025 23:26:04
SAMPEL 9 JAM	20.8	1896.4	18404.8910	33.5	1.12417	10/12/2025 00:07:24
		Mean	18371.4877			
		Std Dev.	33.9460			
		%RSD	0.1848			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 9 JAM	10.0	428.8	5663.1857		1.09526	10/11/2025 22:44:45
SAMPEL 9 JAM	10.1	407.8	5660.0546		1.11581	10/11/2025 23:26:04
SAMPEL 9 JAM	10.0	394.0	5663.6178		1.12722	10/12/2025 00:07:24
		Mean	5662.2861			
		Std Dev.	1.9445			
		%RSD	0.0343			



Cross Sequence Summary Report



Data file:

E:\CDS\Projects\AD\AD 2025\October 2025\Results\VMA
Methisoprinol_091025_VMA_Methisoprinol_Kadar_Moa.rsl\SAMPEL 12
JAM78P1-E2\scientist1.d

Sample name: SAMPEL 12 JAM

Instrument: LC 1260 UV

Injection date: 2025-10-12 01:50:13+07:00

Acq. method: Methisoprinol_Kadar_Moa.amx

Analysis method: PM_VMA

Last changed: 2025-10-17 19:09:45+07:00

Location: P1-E2

Injection: 1 of 1

Injection volume: 20.000

Acq. operator: scientist

Column name: Purophare RP 18

Column Serial No: 310767

Column Length: 150.0 mm

Column Diameter: 4.6 mm

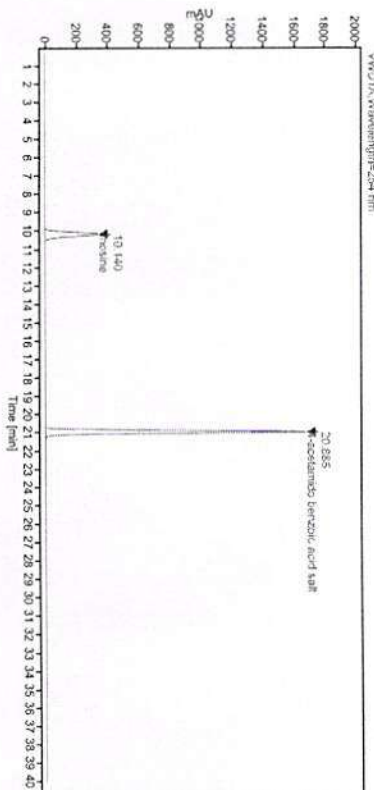
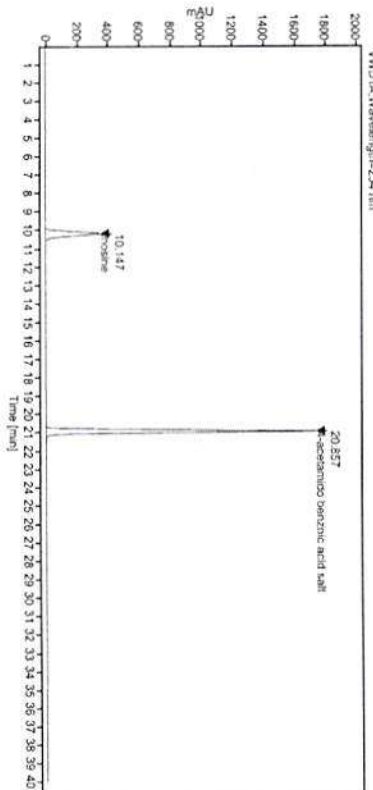
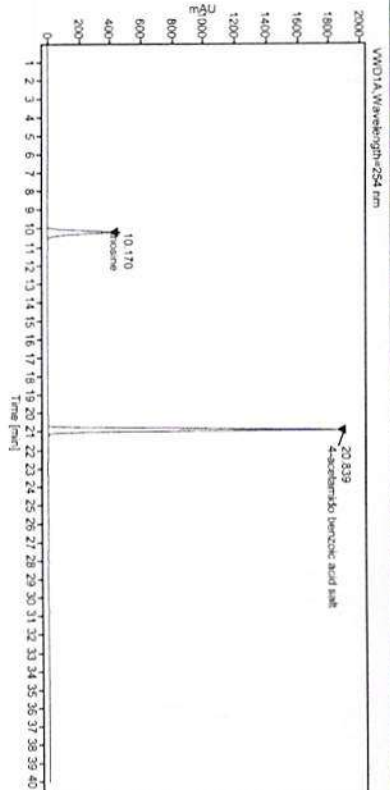
Name: 4-acetamido benzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 12 JAM	20.8	1851.3	18402.8792	33.5	1.13367	10/12/2025 01:50:13
SAMPEL 12 JAM	20.9	1739.7	18462.8813	30.3	1.14033	10/12/2025 02:31:33
SAMPEL 12 JAM	20.9	1682.6	18478.5075	29.6	1.13198	10/12/2025 03:12:52
		Mean	18448.0893			
		Std Dev.	39.9251			
		%RSD	0.2164			

Name: Iosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPEL 12 JAM	10.2	399.4	5656.4327		1.12458	10/12/2025 01:50:13
SAMPEL 12 JAM	10.1	355.1	5664.9486		1.14126	10/12/2025 02:31:33
SAMPEL 12 JAM	10.1	348.1	5667.1981		1.14433	10/12/2025 03:12:52
		Mean	5662.8598			
		Std Dev.	5.6785			
		%RSD	0.1003			

Cross Sequence Summary Report



Cross Sequence Summary Report



Cross Sequence Summary Report



Data file:

E:\CDSP\Project\ADAD 2025\October 2025\Results\VMA
Methisoprinol_091025_VMA_Methisoprinol_Kadar_MoA.rsl\SAMPLEL 24
JAM102P1-EZscientist.d

Sample name:

SAMPLEL 24 JAM

Injection:

1 of 1

Instrument:

LC 1260 UV

Injection volume:

20.000

Injection date:

2025-10-12 16:56:58+07:00

Acq. operator:

scientist

Acq. method:

Methisoprinol_Kadar_MoA.amx

Column name:

Purosphere RP 18
Endcapped (K53)

Analysis method:

PM_VMA
Methisoprinol_MoA.pmx

Column Serial No

310767

Last changed:

2025-10-17 19:09:45+07:00

Column Length :

150.0 mm

Location:

P1-E2

Column Diameter :

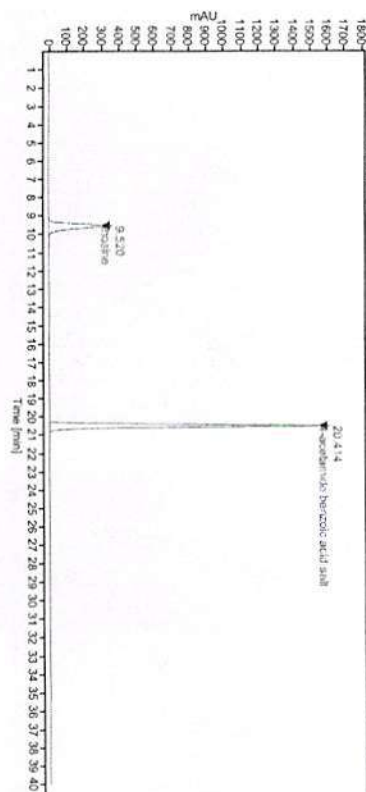
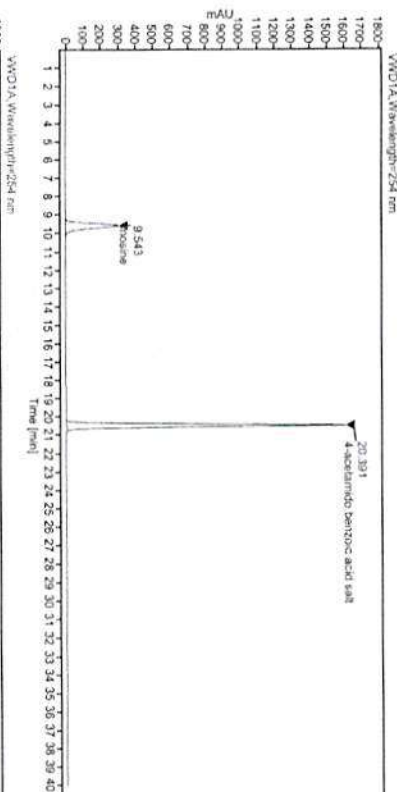
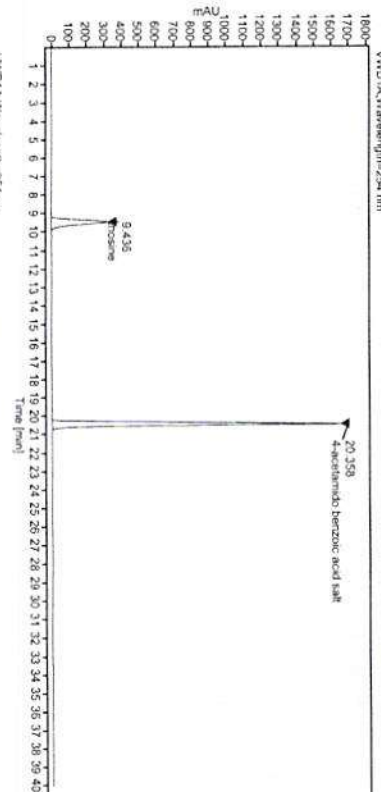
4.6 mm

Name: 4-acetamidobenzoic acid salt

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLEL 24 JAM	20.4	1654.6	18535.0348	28.9	1.18243	10/12/2025 16:56:58
SAMPLEL 24 JAM	20.4	1610.3	18521.4175	27.5	1.19825	10/12/2025 17:38:20
SAMPLEL 24 JAM	20.4	1549.2	18572.8659	26.6	1.22492	10/12/2025 18:19:40
		Mean	18543.1061			
		Std Dev.	26.6570			
		%RSD	0.1438			

Name: Inosine

Name	RT	Height	Area	Resolution	Tail Factor	Injection Acquired Date
SAMPLEL 24 JAM	9.4	325.4	5675.9402		1.18992	10/12/2025 16:56:58
SAMPLEL 24 JAM	9.5	309.4	5688.6521		1.21037	10/12/2025 17:38:20
SAMPLEL 24 JAM	9.5	298.6	5694.0652		1.22320	10/12/2025 18:19:40
		Mean	5686.2192			
		Std Dev.	9.3042			
		%RSD	0.1636			



Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

PROSEDUR VALIDASI METODE ANALISIS BAHAN BAKU

Nama zat aktif : *Methisoprinol*

Tanggal Analisis : *08 Oktober 2025 - 12 Oktober 2025*

Andev Scientist : *Sri Komala*

Parameter : UKS, Spesifisitas, Linieritas, Akurasi, Ripitabilitas, Presisi antara 1, *Robustness*

1. INFORMASI STANDAR DAN SAMPEL

Reference Standard	Nama	<i>Methisoprinol</i>
	No. Batch/Lot	<i>AB0122678</i>
	Manufacturing Date	<i>Current Lot</i>
	Expiry Date	<i>Current Lot</i>
	Manufacturer	<i>BPF1</i>
Reference Standard	Nama	<i>Indosine</i>
	No. Batch/Lot	<i>2023-CPD-018</i>
	Manufacturing Date	<i>26 JANUARI 2023</i>
	Expiry Date	<i>29 JANUARI 2027</i>
	Manufacturer	<i>TRC</i>
Sampel	Nama	<i>Methisoprinol</i>
	No. Batch/Lot	<i>MTP 250225</i>
	Manufacturing Date	
	Expiry Date	<i>30 April 2028</i>
	Manufacturer	<i>Varbids</i>

2. REFERENSI PROSEDUR METODE ANALISIS

Pengujian	Referensi
Kadar Bahan Baku <i>Methisoprinol</i>	<i>In House Method Mengacu Analytical Method of Manufacturer Tahun 2023 (ABC Farmaceutici)</i>

3. PARAMETER PENGUJIAN

REAGEN					
Nama	Grade	Manufacturer	No. Batch/Lot	Expiry Date	Open Date
<i>Potassium dihydrogen phosphate</i>	<i>Analysis</i>	<i>Merck</i>	<i>AM 2015173 926</i>	<i>30 NOV 2028</i>	<i>30 Sep 2025</i>
<i>Ortho phosphoric acid 80%</i>	<i>Analysis</i>	<i>Merck</i>	<i>K53202673 110</i>	<i>31 Agu 2027</i>	<i>28 Apr 2025</i>

Lampiran 8 Protap No. PG-AD-116-00 (*Laboratory Worksheet* Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Methanol	LC	Merck	J1382207448	30 NOV 2027	09 Okt 2015
Purified water	LC	Fresh			

INSTRUMENTASI			
Nama Instrumen	Brand	No. Alat	Tanggal Batas Kalibrasi
HPLC	Agilent Infinity II 1260	PI-AD-HPC-044-E	02 Agu 2026
Timbangan	Sartorius BCE2241-15	PI-AD-TBG-062	04 sep 2026
pH Meter	Mettler Toledo	PI-AD-PHM-102-E	30 Jan 2026
Sonikator	Power Sonic 420	PI-AD-UTR-056	NA
Arium	Sartorius	PI-AD-ARC-049	NA

SISTEM INSTRUMENTASI				
Parameter				Aktual
Instrumen	HPLC Agilent Infinity II			Sesuai/Tidak* Jika Tidak :
Kolom	L1; 4,6 mm x 15 cm (5µm)			Brand kolom : <i>supelco</i> Serial number : <i>310767</i> Sesuai/Tidak* Jika Tidak :
Fase Gerak	Waktu (menit)	Larutan Fase Gerak A (%)	Larutan Metanol (%)	Sesuai/Tidak* Jika Tidak :
	5	95	5	
	10	90	10	
	25	40	60	
	32	40	60	
	35	95	5	
	40	95	5	

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Pelarut	Purified water	Sesuai/Tidak* Jika Tidak
Suhu Kolom	25 °C	Sesuai/Tidak* Jika Tidak
Suhu auto sampler	20 °C	Sesuai/Tidak* Jika Tidak <i>Tidak ada suhu auto sampler</i>
Laju Alir	1 mL/menit	Sesuai/Tidak* Jika Tidak :
Detektor	254 nm	Sesuai/Tidak* Jika Tidak :
Volume Injeksi	20µL	Sesuai/Tidak* Jika Tidak :
Retention time	<i>inosine = 9.4 menit ; 4-Acetamido Benzoic Acid Salt = 20.13 Menit</i>	
Runtime/End time	40 menit	Sesuai/Tidak* Jika Tidak :

*) Lingkari yang sesuai

Jika tidak sesuai, berikan keterangan aktual pengerjaan

PREPARASI LARUTAN		
Prosedur	Aktual	
Fase Gerak A 1. Timbang 2.65 g <i>potassium dihydrogen phosphate</i> masukkan ke dalam <i>beaker glass</i> 1000 mL. 2. Larutkan dan encerkan dengan 1000 mL air, aduk hingga homogen. 3. Atur pH larutan dengan penambahan <i>ortho phosphoric acid</i> 80% hingga dicapai pH 3.5. Saring dan <i>degass</i> . Fase Gerak B Metanol P Pelarut <i>Purified water.</i>	Fase Gerak A	
	<i>Potassium Dihydrogen Phosphate</i>	<i>13 250,1</i> mg
	<i>Purified water</i>	<i>5000</i> mL
	<i>ortho phosphoric acid</i> 80%	<i>12</i> Tetes
	pH larutan	<i>3.5</i>
	Analisis (Inisial) : <i>SKA</i>	
	TTD	Tgl Analisis
	<i>SKA</i>	<i>08 Okt 2025</i>
	Diperiksa oleh : <i>3/11/25</i> <i>KARYA</i>	

Lampiran 8 Protap No. PG-AD-116-00 (*Laboratory Worksheet* Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

SPESIFISITAS							
Prosedur	Aktual						
Larutan Fase Gerak Suntikkan 20 µL larutan Fase gerak yang sudah disaring dengan <i>membrane filter</i> 0,45 µm ke dalam alat HPLC yang telah dikondisikan. Larutan Pelarut Suntikkan 20µL larutan Pelarut yang sudah disaring dengan <i>membrane filter</i> 0,45 µm ke dalam alat HPLC yang telah dikondisikan.	<table border="1"> <tr> <td colspan="2">Analisis (Inisial) : <i>SKA</i></td></tr> <tr> <td>TTD</td><td>Tgl Analisis</td></tr> <tr> <td><i>gh</i></td><td><i>08 Okt 2025</i></td></tr> </table> Diperiksa oleh : <i>03/25</i> <i>PAB</i>	Analisis (Inisial) : <i>SKA</i>		TTD	Tgl Analisis	<i>gh</i>	<i>08 Okt 2025</i>
Analisis (Inisial) : <i>SKA</i>							
TTD	Tgl Analisis						
<i>gh</i>	<i>08 Okt 2025</i>						

UJI KESESUAIAN SISTEM													
Prosedur	Aktual												
Larutan Identifikasi Inosine 1. Timbang 120,3 mg Inosine RS masukkan ke dalam labu ukur 50 mL. 2. Larutkan dengan 25 mL <i>methanol</i>, kocok hingga larut. 3. Tambahkan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen ($C_{Inosine RS} = 2,406 \text{ mg/mL}$). 4. Pipet 1,0 mL Larutan masukkan ke dalam labu ukur 20 mL. 5. Tambahkan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen. 6. Saring larutan menggunakan <i>membrane filter</i> 0,45 µm ke vial LC ($C_{Inosine RS} = 0,1203 \text{ mg/mL}$).	<table border="1"> <tr> <td colspan="2">Identifikasi Inosine</td></tr> <tr> <td>Bobot <i>Inosine RS</i></td><td><i>120,3</i> mg</td></tr> <tr> <td>Volume <i>Methanol</i></td><td><i>25</i> mL</td></tr> <tr> <td>Volume Labu</td><td><i>50</i> mL</td></tr> <tr> <td>Volume Pemipetan</td><td><i>1,0</i> mL</td></tr> <tr> <td>Volume Labu</td><td><i>20,0</i> mL</td></tr> </table>	Identifikasi Inosine		Bobot <i>Inosine RS</i>	<i>120,3</i> mg	Volume <i>Methanol</i>	<i>25</i> mL	Volume Labu	<i>50</i> mL	Volume Pemipetan	<i>1,0</i> mL	Volume Labu	<i>20,0</i> mL
Identifikasi Inosine													
Bobot <i>Inosine RS</i>	<i>120,3</i> mg												
Volume <i>Methanol</i>	<i>25</i> mL												
Volume Labu	<i>50</i> mL												
Volume Pemipetan	<i>1,0</i> mL												
Volume Labu	<i>20,0</i> mL												

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Linieritas 75%

1. Pipet 0,75 mL Larutan Induk *Methisoprinol* RS masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Inosine} = 0,375 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 0,375 \text{ mg/mL}$)

Linieritas 100%

1. Pipet 1,0 mL Larutan Induk *Methisoprinol* RS masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$)

Linieritas 125%

1. Pipet 1,25 mL Larutan Induk *Methisoprinol* RS masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Inosine} = 0,625 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 0,625 \text{ mg/mL}$)

Linieritas 150%

1. Pipet 1,5 mL Larutan Induk *Methisoprinol* RS masukkan ke dalam labu ukur 5 mL.
2. Tambahkan *purified water* hingga tanda batas kemudian homogenkan.
3. Saring larutan menggunakan *membrane filter* 0,45µm ke vial LC. ($C_{Inosine} = 0,75 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 0,75 \text{ mg/mL}$)

Linieritas 75%

Volume Pemipetan	... 0,75 ... mL
Volume Labu	... 5 ... mL

Linieritas 100%

Volume Pemipetan	... 1,0 ... mL
Volume Labu	... 5 ... mL

Linieritas 125%

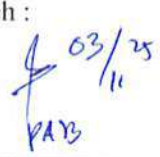
Volume Pemipetan	... 1,25 ... mL
Volume Labu	... 5 ... mL

Linieritas 150%

Volume Pemipetan	... 1,5 ... mL
Volume Labu	... 5 ... mL

Lampiran 8 Protap No. PG-AD-116-00 (*Laboratory Worksheet* Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Analisis (Inisial) : SKA	
TTD	Tgl Analisis
zh	10 Okt 2025
Diperiksa oleh :  PAB	

AKURASI DAN RIPITABILITAS							
Prosedur	Aktual						
Larutan standar Lakukan sesuai prosedur Uji Kesesuaian Sistem							
Larutan Induk Sampel - Timbang 125 mg sampel <i>Methisoprinol</i> masukkan ke dalam labu ukur 50 mL. - Larutkan dengan 25,0 mL <i>purified water</i>, kocok hingga larut. - Tambahkan dengan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen. ($C_{Inosine} = 2,5 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 2,5 \text{ mg/mL}$)	<table border="1"> <tr> <th colspan="2">Larutan Induk Sampel</th></tr> <tr> <td>Bobot sampel</td><td>125,0 mg</td></tr> <tr> <td>Labu Ukur</td><td>50 mL</td></tr> </table>	Larutan Induk Sampel		Bobot sampel	125,0 mg	Labu Ukur	50 mL
Larutan Induk Sampel							
Bobot sampel	125,0 mg						
Labu Ukur	50 mL						
Akurasi 80% - Pipet 1,6 mL Larutan Induk Sampel <i>Methisoprinol</i> masukkan ke dalam labu ukur 10 mL. - Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. - Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,4 \text{ mg/mL}$; $C_{4\text{-acetamido benzoic acid salt}} = 0,4 \text{ mg/mL}$)	<table border="1"> <tr> <th colspan="2">Akurasi 80%</th></tr> <tr> <td>Volume Pemipetan</td><td>1,6 mL</td></tr> <tr> <td>Labu Ukur</td><td>10 mL</td></tr> </table>	Akurasi 80%		Volume Pemipetan	1,6 mL	Labu Ukur	10 mL
Akurasi 80%							
Volume Pemipetan	1,6 mL						
Labu Ukur	10 mL						

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

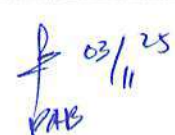
Laboratory Worksheet

Akurasi 100% 1. Pipet 2,0 mL Larutan Induk Sampel masukkan ke dalam labu ukur 10 mL. 2. Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. 3. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$) Akurasi 120% 1. Pipet 2,4 mL Larutan Induk Sampel masukkan ke dalam labu ukur 10 mL. 2. Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. 3. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,6 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,6 \text{ mg/mL}$)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Akurasi 100%</th> </tr> <tr> <td style="width: 60%; padding: 2px;">Volume Pemipetan</td> <td style="padding: 2px;">.....2,0..... mL</td> </tr> <tr> <td style="padding: 2px;">Labu Ukur</td> <td style="padding: 2px;">.....10..... mL</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Akurasi 120%</th> </tr> <tr> <td style="width: 60%; padding: 2px;">Volume Pemipetan</td> <td style="padding: 2px;">.....2,4..... mL</td> </tr> <tr> <td style="padding: 2px;">Labu Ukur</td> <td style="padding: 2px;">.....10..... mL</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 2px;">Analisis (Inisial) : SKA</td> </tr> <tr> <td style="width: 50%; padding: 2px;">TTD</td> <td style="padding: 2px;">Tgl Analisis</td> </tr> <tr> <td style="height: 40px; vertical-align: middle; text-align: center; padding: 2px;"> </td> <td style="padding: 2px;">03 Okt 2025</td> </tr> </table> Diperiksa oleh : 03/11/25 PAB	Akurasi 100%		Volume Pemipetan	2,0..... mL	Labu Ukur	10..... mL	Akurasi 120%		Volume Pemipetan	2,4..... mL	Labu Ukur	10..... mL	Analisis (Inisial) : SKA		TTD	Tgl Analisis		03 Okt 2025
Akurasi 100%																			
Volume Pemipetan	2,0..... mL																		
Labu Ukur	10..... mL																		
Akurasi 120%																			
Volume Pemipetan	2,4..... mL																		
Labu Ukur	10..... mL																		
Analisis (Inisial) : SKA																			
TTD	Tgl Analisis																		
	03 Okt 2025																		

PRESISI ANTARA 1									
Prosedur	Aktual								
Larutan Standar Lakukan sesuai prosedur Uji Kesesuaian Sistem. Presiisi Antara 1 1. Timbang 25 mg sampel <i>Methisoprinol</i>, masukkan ke dalam labu ukur 50 mL. 2. Larutkan dengan 25 mL <i>purified water</i>, kocok hingga larut. 3. Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Presisi Antara 1</th> </tr> <tr> <td style="width: 60%; padding: 2px;">Bobot Sampel 1</td> <td style="padding: 2px;">.....25,0..... mg</td> </tr> <tr> <td style="padding: 2px;">Bobot Sampel 2</td> <td style="padding: 2px;">.....25,0..... mg</td> </tr> <tr> <td style="padding: 2px;">Bobot Sampel 3</td> <td style="padding: 2px;">.....25,0..... mg</td> </tr> </table>	Presisi Antara 1		Bobot Sampel 1	25,0..... mg	Bobot Sampel 2	25,0..... mg	Bobot Sampel 3	25,0..... mg
Presisi Antara 1									
Bobot Sampel 1	25,0..... mg								
Bobot Sampel 2	25,0..... mg								
Bobot Sampel 3	25,0..... mg								

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

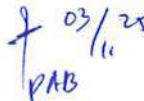
Laboratory Worksheet

4. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$).	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Bobot Sampel 4</td> <td style="width: 40%;">.....25,0..... mg</td> </tr> <tr> <td>Bobot Sampel 5</td> <td>.....25,0..... mg</td> </tr> <tr> <td>Bobot Sampel 6</td> <td>.....25,0..... mg</td> </tr> <tr> <td>Volume Labu</td> <td>.....25,0..... mL</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Analisis (Inisial) : SKA</td> </tr> <tr> <td style="width: 50%;">TTD</td> <td style="width: 50%;">Tgl Analisis</td> </tr> <tr> <td style="text-align: center; height: 40px;">  </td> <td style="text-align: center; height: 40px;"> 10 Okt 2025 </td> </tr> </table> Diperiksa oleh : 	Bobot Sampel 4	25,0..... mg	Bobot Sampel 5	25,0..... mg	Bobot Sampel 6	25,0..... mg	Volume Labu	25,0..... mL	Analisis (Inisial) : SKA		TTD	Tgl Analisis		10 Okt 2025
Bobot Sampel 4	25,0..... mg														
Bobot Sampel 5	25,0..... mg														
Bobot Sampel 6	25,0..... mg														
Volume Labu	25,0..... mL														
Analisis (Inisial) : SKA															
TTD	Tgl Analisis														
	10 Okt 2025														

ROBUSTNESS													
Prosedur	Aktual												
Larutan Induk Standar Gunakan larutan induk <i>methisoprinol</i> RS pada prosedur Linieritas. Robustness Larutan Standar - Pipet 1,0 mL Larutan Induk <i>Methisoprinol</i> RS masukkan ke dalam labu ukur 5 mL. - Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. - Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$) Robustness Larutan Sampel - Timbang 25 mg sampel <i>Methisoprinol</i>, masukkan ke dalam labu ukur 50 mL.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: center; padding: 5px;">Robustness Larutan Standar</th> </tr> <tr> <td style="width: 60%;">Volume Pemipetan</td> <td style="width: 40%;">.....1,0.....mL</td> </tr> <tr> <td>Volume Labu</td> <td>.....5.....mL</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: center; padding: 5px;">Robustness Larutan Sampel</th> </tr> <tr> <td style="width: 60%;">Bobot Sampel</td> <td style="width: 40%;">.....25,0.....mg</td> </tr> <tr> <td>Volume Labu</td> <td>.....50.....mL</td> </tr> </table>	Robustness Larutan Standar		Volume Pemipetan	1,0.....mL	Volume Labu	5.....mL	Robustness Larutan Sampel		Bobot Sampel	25,0.....mg	Volume Labu	50.....mL
Robustness Larutan Standar													
Volume Pemipetan	1,0.....mL												
Volume Labu	5.....mL												
Robustness Larutan Sampel													
Bobot Sampel	25,0.....mg												
Volume Labu	50.....mL												

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

2. Larutkan dengan 25 mL <i>purified water</i>, kocok hingga larut. 3. Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. 4. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$).	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Analisis (Inisial) : SKA</td> </tr> <tr> <td style="width: 50%;">TTD</td> <td style="width: 50%;">Tgl Analisis</td> </tr> <tr> <td style="text-align: center; height: 50px;">  </td> <td style="text-align: center; vertical-align: middle;"> 10 Okt 2025 </td> </tr> </table> Diperiksa oleh :  PAB	Analisis (Inisial) : SKA		TTD	Tgl Analisis		10 Okt 2025
Analisis (Inisial) : SKA							
TTD	Tgl Analisis						
	10 Okt 2025						

SEQUENCE DAN KRITERIA PENERIMAAN

A. SEQUENCE

Komponen	Replikasi Preparasi	Replikasi Injeksi
Spesifisitas Pelarut	1	2
Spesifitas Fase Gerak	1	2
Uji Kesesuaian Sistem dan Larutan Standar	1	5
Identifikasi <i>Inosine</i>	1	3
Linieritas 50%	1	3
Linieritas 75%	1	3
Linieritas 100%	1	3
Linieritas 125%	1	3
Linieritas 150%	1	3
Larutan Akurasi 80 %	3	1
Larutan Akurasi 100 %	3	1
Larutan Akurasi 120%	3	1
Presisi antara 1	6	1
Robustness Larutan Standar 0 Jam	1	3
Robustness Larutan Standar 3 Jam	1	3
Robustness Larutan Standar 6 Jam	1	3
Robustness Larutan Standar 9 Jam	1	3
Robustness Larutan Standar 12 Jam	1	3
Robustness Larutan Standar 24 Jam	1	3
Robustness Larutan Sampel 0 Jam	1	3
Robustness Larutan Sampel 3 Jam	1	3
Robustness Larutan Sampel 6 Jam	1	3
Robustness Larutan Sampel 9 Jam	1	3
Robustness Larutan Sampel 12 Jam	1	3
Robustness Larutan Sampel 24 Jam	1	3

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

B. KRITERIA PENERIMAAN

Komponen	Kriteria Penerimaan
Uji Kesesuaian Sistem dan Larutan Standar	% RSD <i>Inosine</i> dan <i>4-acetamido benzoic acid salt</i> : $\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan <i>4-acetamido benzoic acid salt</i> : 0,8 – 1,5
Spesifisitas Pelarut	Tidak ada Interferensi dari pelarut
Spesifisitas Fase gerak	Tidak ada Interferensi dari fase gerak
Linieritas	$R^2 : \geq 0,990$
Akurasi	Rata-rata <i>Recovery</i> : 98,0 – 102,0 %
Presisi Rিপিতাৰিতা	RSD rata-rata <i>recovery</i> : $\leq 2,0\%$
Presisi antara 1	Kadar <i>Inosine</i> : 95,0 – 105,0%, <i>on dried basis</i>
	Kadar <i>4-acetamido benzoic acid salt</i> : 95,0 – 105,0%, <i>on dried basis</i>
Robustnes	% <i>Recovery</i> larutan standar dan larutan sampel : 98,0 – 102,0%

RUMUS PERHITUNGAN

1. Akurasi

Bobot *Recovery* dari *Inosine* dan *4-acetamido benzoic acid salt*:

$$\text{Bobot Recovery} = \frac{r_u}{r_s} \times \frac{D_u}{D_s} \times W_s$$

Keterangan:

r_u = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan akurasi

r_s = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

D_u = Faktor pengenceran dari larutan akurasi

D_s = Faktor pengenceran dari larutan standar

W_s = Bobot penimbangan dari larutan standar (mg)

%*Recovery* dari *Inosine* dan *4-acetamido benzoic acid salt*:

$$\% \text{ Recovery} = \frac{\text{Bobot recovery}}{\text{Bobot aktual}} \times 100\%$$

Laboratory Worksheet

2. Presisi

% kadar *Inosine* dan *4-acetamido benzoic acid salt* dengan rumus:

$$\% \text{ Kadar} = \frac{ru}{rs} \times \frac{Ws}{Wu} \times \frac{P}{(100 - KF)} \times \frac{Du}{Ds} \times 100$$

Keterangan :

ru = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan sampel

rs = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

Ws = Bobot penimbangan dari larutan standar (mg)

Wu = Bobot penimbangan dari larutan sampel (mg)

P = Potensi Methisoprinol RS (%)

Du = Faktor pengenceran dari larutan sampel

Ds = Faktor pengenceran dari larutan standar

KF = Kadar air sampel

3. Robustness Larutan Standar

$$\% \text{ Recovery Standar} = \frac{rs \text{ jam ke } - (n)}{rs \text{ jam ke } - 0} \times 100\%$$

Keterangan :

rs = Respon area *peak inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

4. Robustness Larutan Sampel

$$\% \text{ Recovery Sampel} = \frac{ru \text{ jam ke } - (n)}{ru \text{ jam ke } - 0} \times 100\%$$

Keterangan :

ru = Respon area *peak inosine* dan *4-acetamido benzoic acid salt* dari larutan sampel

DATA PENIMBANGAN

Nama Bahan Baku : Methisoprinol
 No. LSA : B4503760
 Pengujian : UKS (standar)

RS Methisoprinol
 BPFI

15-Sep-2025 15:58
 Sartorius
 Mod. BCE224I-1S
 Ser. no. 44105366
 APC 01-76-05.03.03
 BAC 00-59-05.03.03
 ID PI-AD-TBG-062

G + 25.0 mg

15-Sep-2025 15:58
 Name: Jh SKA
 15 SEP 2025

methisoprinol
 AB0122678

standar

06-Oct-2025 19:45
 Sartorius
 Mod. BCE224I-1S
 Ser. no. 45007949
 APC 01-76-05.06.01
 BAC 00-59-05.06.01
 ID PI-AD-TBG-065

N + 10.0 mg

06-Oct-2025 19:45
 Name: Jell
 JA

RS inosine (TPC)
 58-63-9

29-Sep-2025 15:28
 Sartorius
 Mod. BCE224I-1S
 Ser. no. 45007949
 APC 01-76-05.06.01
 BAC 00-59-05.06.01
 ID PI-AD-TBG-065

G + 120.3 mg

29-Sep-2025 15:28
 Name: Jh SKA
 29 SEP 2025

Dilakukan Oleh:	Diperiksa Oleh:
Jh SKA 09 Okt 15 SEP 2025 SKA 09 Okt 2025	Jh 03/25 PAB

DATA PENIMBANGAN

Nama Bahan Baku : Methisoprimol
 No. LSA : B4503760
 Pengujian : Fase Gerak

KH200a
 AM2015173 426

08-Oct-2025 08:12

Sartorius

Mod. BCE224I-1S

Ser. no. 44105366

APC 01-76-05.03.03

BAC 00-59-05.03.03

ID PI-AD-TBG-062

G + 13250.1 mg

08-Oct-2025 08:12

Name: SKA
 08 Oct 2025

Date / Time 08-OCT-2025

09:00:18

Sample ID 2apar pH 3.5

Comment

Result status

OK

Method ID pH method

Measurement type

pH

Sensor name ExpertProISM

Measurement result

3.50 pH

wp 210.7 mV

Temperature 26.0 °C(ATO)

Endpoint Manual/600 (

seconds)

Stable status

Yes (Strict)

Signature

SKA
 08 Oct 2025

Dilakukan Oleh:	Diperiksa Oleh:
SKA 08 Oct 2025	03/11/25 VAB

DATA PENIMBANGAN

Nama Bahan Baku : Methisoprinol
 No. LSA : B4503760
 Pengujian : Akurasi dan Presisi Antara 1

AKURASI

LSA: B4503760

09-Oct-2025 08:58
 Sartorius
 Mod. BCE224I-1S
 Ser. no. 44105366
 APC 01-76-05.03.03
 BAC 00-59-05.03.03
 ID PI-AD-TBG-062

N + 125.0 mg

09-Oct-2025 08:58

Name: *SKA*
10 Okt 2025

Presisi Antara 1

LSA: B4503760

10-Oct-2025 14:13
 Sartorius
 Mod. BCE224I-1S
 Ser. no. 44105366
 APC 01-76-05.03.03
 BAC 00-59-05.03.03
 ID PI-AD-TBG-062

Comp01+ 25.0 mg
 Comp02+ 25.0 mg
 Comp03+ 25.0 mg
 Comp04+ 25.0 mg
 Comp05+ 25.0 mg
 Comp06+ 25.0 mg

n 6
 x + 25.00 mg
 s 0.00 mg
 sRel 0.00 %
 Sum + 150.0 mg
 Min + 25.0 mg
 Max + 25.0 mg
 Diff 0.0 mg

10-Oct-2025 14:19

Name: *SKA*
10 Okt 2025

Dilakukan Oleh:	Diperiksa Oleh:
<i>SKA</i> <i>10 Okt 2025</i>	<i>03/11</i> <i>PAB</i>

DATA PENIMBANGAN

Nama Bahan Baku : Methisoprinol
No. LSA : B4503760
Pengujian : Robustness

Robustness

LSA : B4503760

10-Oct-2025 14:22

Sartorius

Mod. BCE224I-1S

Ser. no. 44105366

APC 01-76-05.03.03

BAC 00-59-05.03.03

ID FI-AD-T8G-062

G + 25.0 mg

10-Oct-2025 14:22

Name: SKA
10 Okt 2025

Dilakukan Oleh:	Diperiksa Oleh:
SKA 10 Okt 2025	03/25 YAB

LAPORAN VALIDASI METODE ANALISIS BAHAN BARU
KADAR METHISOPRINOLO

Tanggal Analisis : 14 Oktober 2025 - 15 Oktober 2025
AD Scientist : Jelly Martha Helma
Parameter : UKS (Peak Identifikasi dan Larutan standar), Spesifikasi, Presisi Antara 2

Informasi Reference Standard				Informasi Sampel			
Nama	Methisoprinol	Nama	Inosine	Nama	Methisoprinol		
No. Lot	AD0122678	No. Lot	2023-CPO-018	No. Batch	MTT250225		
Potensi	99.56%	Potensi	99.94%	Expired date	30 April 2028		
Expired date	Current Lot	Expired date	Current Lot	Manufacturer	Limboos		
Manufacturer	BPTI	Manufacturer	BPTI				

*PEAK IDENTIFIKASI				
No.	Inosine RS (mg)	Dilution Inosine RS	Kons. Inosine RS (mg/mL)	Retention Time (Menit)
1				9.0
2	120	1000	0.120	9.1
3				9.0
Rata-rata				9.0

* LARUTAN STANDAR									
No.	Methisoprinol RS (mg)	Dilution Methisoprinol RS	Kons. Methisoprinol RS (mg/mL)	Retention Time (Menit)	Tailing Factor	Area Inosine	Retention Time (Menit)	Tailing Factor	Area t-Acetaminido benzoic acid salt
1				8.6	1.2	5299.7689	20.3	1.0	18907.0868
2				8.6	1.2	5299.6007	20.3	1.0	18940.6692
3	10	20	0.5	8.6	1.2	5300.5496	20.3	1.0	18903.3153
4				8.6	1.2	5297.9019	20.3	1.0	18900.1594
5				8.6	1.2	5298.9155	20.3	1.0	18906.2249
Rata-rata				8.6	1.2	5299.3473	20.3	1.0	18911.4911
%RSD						0.02%			0.09%
Syarat					0.8 - 1.5	≤1.04 %		0.8 - 1.5	≤1.04 %

*SPESIFISITAS	
Spesifikasi	Area
Pelarat	0.0000
Free Gerak	0.0000

*PRESISI ANTARA 2									
No	Ws	Ds	rs	Retention Time (Menit)	Bobot Sampel (mg)	Du	ru	Retention Time (Menit)	Kadar air (%)
1			5299.7689	8.6	25.0		5297.9736	8.7	99.8%
2			5299.6007	8.6	25.0		5283.4996	8.7	99.6%
3	10	20	5300.5496	8.6	25.0	50	5248.5595	8.8	98.9%
4			5297.9019	8.6	25.0		5223.5045	8.8	98.4%
5			5298.9155	8.6	25.0		5263.5953	8.8	99.2%
6				8.6	25.0		5229.9267	8.8	98.6%
Rata-rata				8.6	25.0		5257.8432	8.8	99.1%
%RSD							0.6%		0.6
Syarat									95.0 - 105.0

4-ACETAMIDO BENZOIC ACID SALT

No	Ws	Ds	rs	Retention Time (Menit)	Bobot Sampel (mg)	Du	ru	Retention Time (Menit)	Kadar air (%)	Kadar (%)
1			18907.0868	20.3	25.0		18948.0351	20.3		100.1%
2			18940.6692	20.3	25.0		19000.0530	20.3		100.3%
3			18903.3153	20.3	25.0		19097.8735	20.4		100.8%
4			18900.1594	20.3	25.0		19005.5239	20.4		100.7%
5			18906.2249	20.3	25.0		19059.9266	20.4		100.6%
6			-	20.3	25.0		19060.6579	20.4		100.5%
Rata-rata			18911.4911	20.3	25.0		19038.6783	20.4		100.5%
% RSD			0.0	0.0	0.0		0.3	0.3		0.3
			Syarat							
			95.0 - 105.0							

Perhitungan

$$\% \text{ Kadar} = \frac{r_u}{r_s} \times \frac{W_s}{W_u} \times \frac{P}{(100 - KF)} \times \frac{D_u}{D_s} \times 100$$

Keterangan :

- r_u = Respon area peak *insuline* dan 4-*acetamido benzoic acid salt* dari larutan sampel
- r_s = Respon area peak *insuline* dan 4-*acetamido benzoic acid salt* dari larutan standar
- W_s = Bobot penimbangan dari larutan standar (mg)
- W_u = Bobot penimbangan dari larutan sampel (mg)
- P = Potensi *Methoprolol* RS (%)
- D_u = Faktor pengenceran dari larutan sampel
- D_s = Faktor pengenceran dari larutan standar
- KF = Kadar air sampel

KOMPARASI PRESENSI ANTARA 1 DAN PRESENSI ANTARA 2

<i>Insuline</i>		Presisi 1 (%)		Presisi 2 (%)	
No	Seri	Sri Komala		Jelly	
1		100.0%		99.8%	
2		99.8%		99.6%	
3		99.9%		98.9%	
4		100.1%		98.4%	
5		100.1%		99.2%	
6		99.7%		98.6%	
Rata-rata 12 data		100%			
% RSD 12 data		0.6%			

4- <i>acetamido benzoic acid salt</i>		Presisi 1 (%)		Presisi 2 (%)	
No	Seri	Sri Komala		Jelly	
1		100.8%		100.1%	
2		100.7%		100.3%	
3		100.9%		100.8%	
4		101.0%		100.7%	
5		101.1%		100.6%	
6		100.5%		100.6%	
Rata-rata 12 data		100.7%			
% RSD 12 data		0.3%			

Kriteria Penerimaan				
Komponen	Parameter	Hasil	Kriteria Penerimaan	Kesimpulan
Larutan Standar	% RSD <i>Inosine</i>	0.02%	$\leq 1.04\%$	Memenuhi Syarat
	% RSD 4-Acetamido benzoic acid	0.09%		Memenuhi Syarat
	Tailing Factor <i>Inosine</i>	1.2		Memenuhi Syarat
	Tailing Factor 4-Acetamido benzoic acid	1.0		Memenuhi Syarat
Larutan Spesifikasi	Interferensi Pelarut	Tidak ada Interferensi	Tidak ada Interferensi	Memenuhi Syarat
	Interferensi Fase Gerak	Tidak ada Interferensi		Memenuhi Syarat
	Kadar <i>Inosine</i>	99.1%		Memenuhi Syarat
	Kadar 4-Acetamido benzoic acid	100.5%		Memenuhi Syarat
Presisi antara 2	RSD <i>Inosine</i> antar analisis	0.6%	$\leq 2.0\%$	Memenuhi Syarat
	RSD 4-Acetamido benzoic acid antar analisis	0.3%		Memenuhi Syarat

Dilakukan oleh :	Diperiksa oleh :	Ditetujui oleh :
22/10/25 DMMH	29/10/25 FAB	20/10/25 Kurniyaningrum

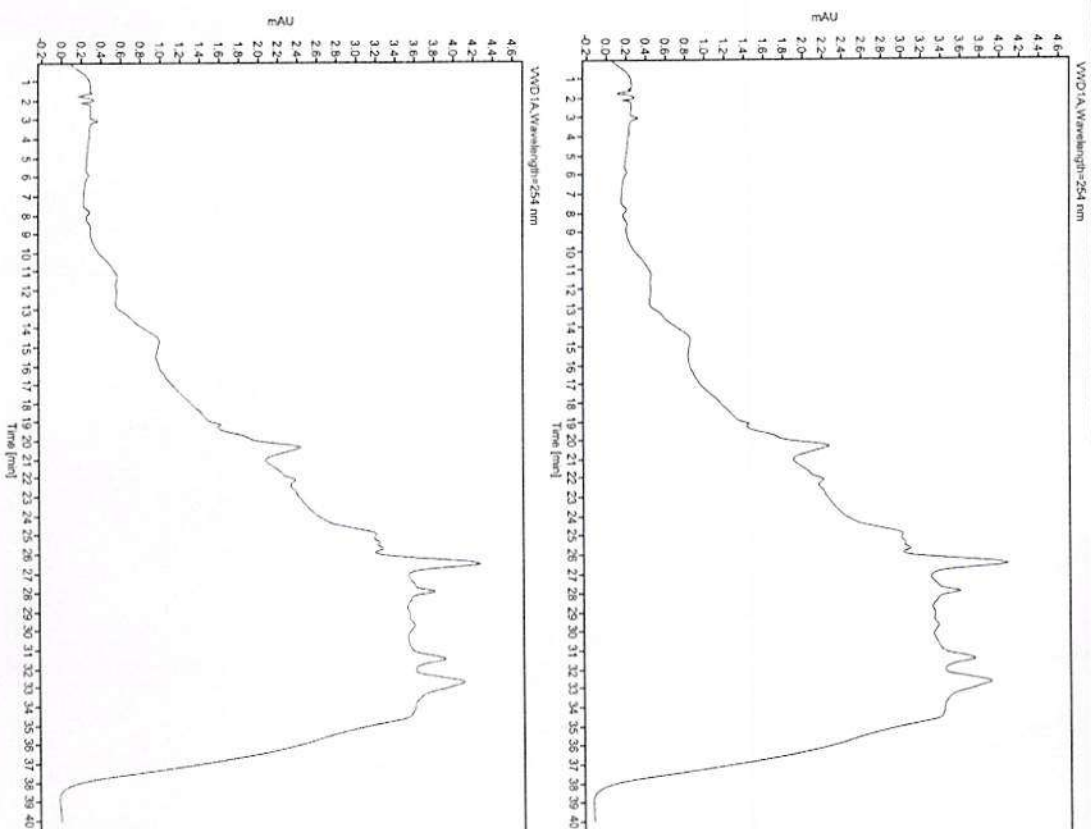
Cross Sequence Summary Report



Data file: D:\CDSP\Projects\October 2025\Results\VMA_Methisoprinol_Kadar\141025_VMA
 Presisi 2 Methisoprinol_Kadar.rsl\2025-10-14 22:32:35+07:00-03.d\

Sample name:	SPESIFISITAS PELARUT	Location:	P1-A2
Instrument:	1260 II - HPLC 06	Injection:	1 of 1
Injection date:	2025-10-14 22:33:48+07:00	Injection volume:	20.0 µL
Acq. method:	Methisoprinol_Kadar_MoA.amx	Acq. operator:	scientist
Analysis method:	*PM_Methisoprinol_Kadar_Presisi 2_MoA.pmx	Column Length	150.0 mm
Last changed:	2025-10-17 18:50:23+07:00	Column Diameter	4.6 mm
Column Name	Purosphere RP 18 Endcapped (K53)	Particle Size	5.0 µm
Serial No	310767		

Cross Sequence Summary Report



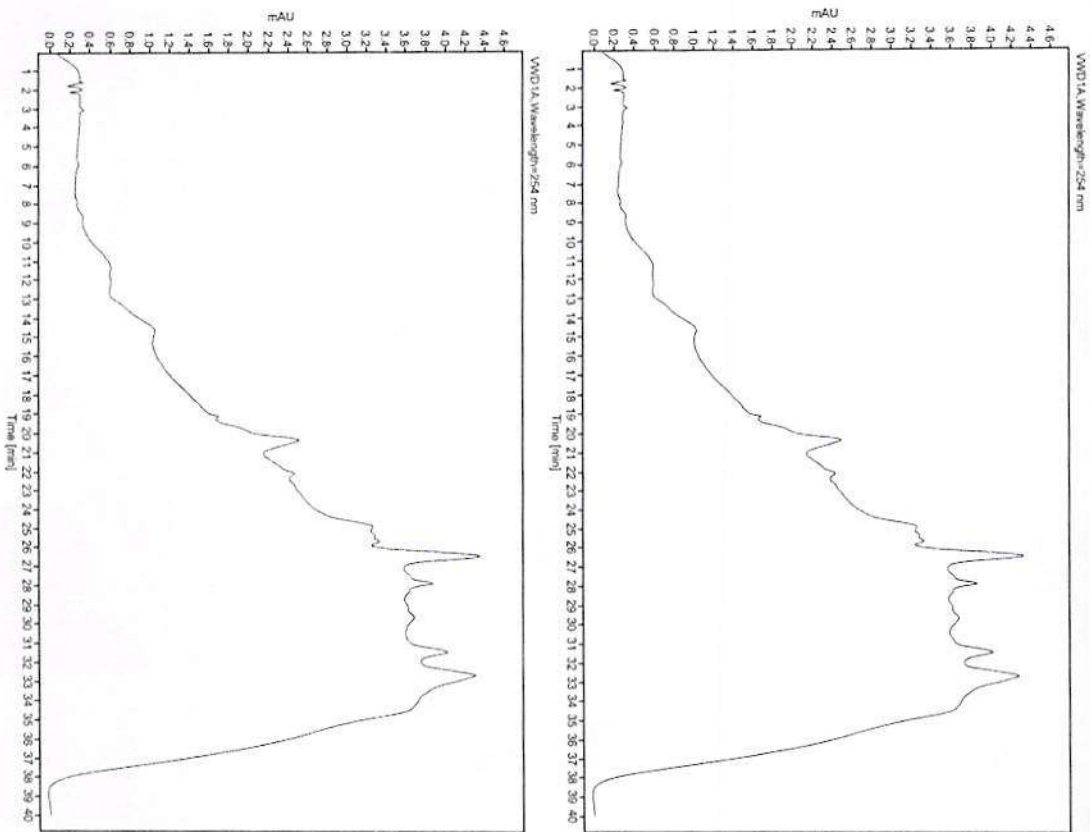
[Signature]

Cross Sequence Summary Report



Data file:	D:\CDSP\Projects\October 2025\Results\VMA_Methisoprinol_Kadar\141025_VMA_Presi1_2_Methisoprinol_Kadar.rst\2025-10-15 00-36-30+07-00-06.dx		
Sample name:	SPESIFISITAS FASE GERAK	Location:	P1-A3
Instrument:	1260 II - HPLC 06	Injection:	1 of 1
Injection date:	2025-10-15 00:37:42+07:00	Injection volume:	20.0 µL
Acq. method:	Methisoprinol_Kadar_MoA.amx	Acq. operator:	scientist
Analysis method:	*PM_Methisoprinol_Kadar_Presi1_2_MoA.pmx	Column Length:	150.0 mm
Last changed:	2025-10-17 18:50:23+07:00	Column Diameter:	4.6 mm
Column Name:	Purosphere RP 18 Endcapped (K53)	Particle Size:	5.0 µm
Serial No	310767		

Cross Sequence Summary Report



mm

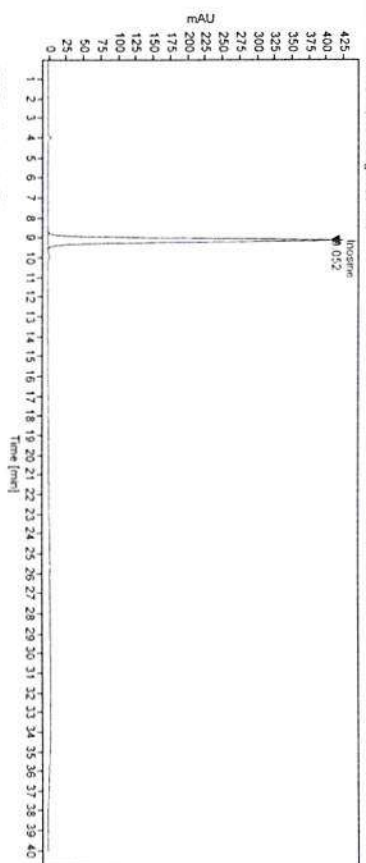
Cross Sequence Summary Report



Data file: D:\CDS\Projects\October 2025\Results\Trial Methisopropinol Kadar\141025_VNA
Presisi 2 Methisopropinol_Kadar.rsl(2025-10-15 02:40:22+07:00:09 dx
Sample name: INOSINE Location: P1-A4
Instrument: 1260 II - HPLC 06 Injection: 1 of 1
Injection date: 2025-10-15 02:41:34+07:00 Injection volume: 20.0 µL
Acq. method: Methisopropinol_Kadar_MoA.amx Acq. operator: scientist
Analysis method: *PM_Methisopropinol_Kadar_Presisi
2_MoA.pmx Column Length: 150.0 mm
Last changed: 2025-10-17 18:50:23+07:00 Column Diameter: 4.6 mm
Column Name: Purosphere RP 18 Endcapped (K53) Particle Size: 5.0 µm
Serial No: 310767

Inosine					
Name	RT	Tail Factor	Resolution	Height	Area
INOSINE	9.0	1.1		405.614	5546.3673
INOSINE	9.1	1.1		406.528	5548.4183
INOSINE	9.0	1.1		405.137	5546.7021
				Mean	5547.1626
				Std Dev.	1.1003
				%RSD	0.0198

Cross Sequence Summary Report



Handwritten signature

Cross Sequence Summary Report



Data file: D:\CDSP\Projects\October 2025\Results\VMA Methisoprinol Kadar\141025_VMA
 Press 2 Methisoprinol_Kadar.rsl\2025-10-15 04:44:12+07:00-12 dx

Sample name: STANDAR Location: P1-A4
 Instrument: 1260 II - HPLC 06 Injection: 1 of 1
 Injection date: 2025-10-15 04:45:22+07:00 Injection volume: 20.0 µL
 Acq. method: Methisoprinol_Kadar_MoA.amx Acq. operator: scientiel
 Analysis method: *P1_Methisoprinol_Kadar_Presi Column length: 150.0 mm
 2_MoA.pmx Column Diameter: 4.6 mm
 Last changed: 2025-10-17 18:50:23+07:00 Particle Size: 5.0 µm
 Column Name: Purosphare RP 18 Endcapped (K53)
 Serial No: 310767

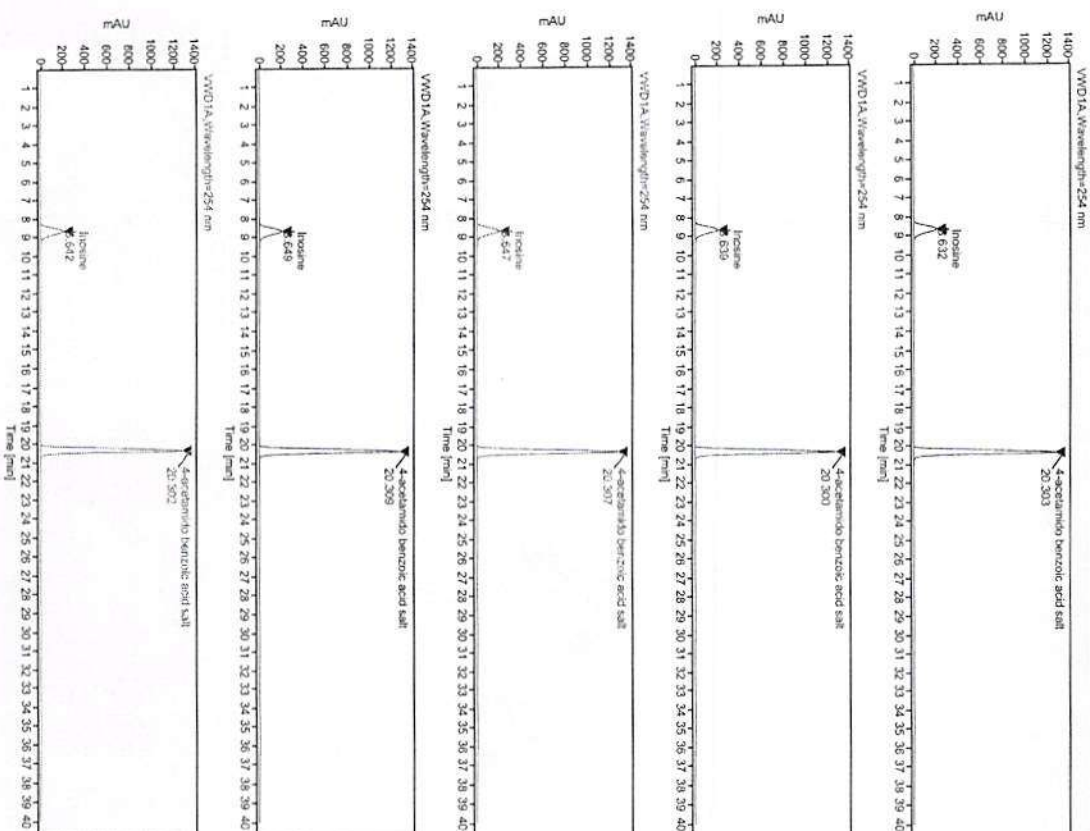
Name: 4-acetamidobenzoic acid salt

Name	RT	Tail Factor	Resolusi	Height	Area	Injection Date
STANDAR	20.3	1.0	21.55951	1278.460	18907.0668	10/15/2025 4:45:22 AM
STANDAR	20.3	1.0	21.51876	1280.040	18940.6592	10/15/2025 5:26:40 AM
STANDAR	20.3	1.0	21.58823	1282.308	18903.3153	10/15/2025 6:07:56 AM
STANDAR	20.3	1.0	21.55195	1280.761	18900.1594	10/15/2025 6:49:13 AM
STANDAR	20.3	1.0	21.56606	1280.640	18906.2249	10/15/2025 7:30:30 AM
				Mean	18911.4911	
				Std Dev.	16.5359	
				%RSD	0.0874	

Name: Inosine

Name	RT	Tail Factor	Resolusi	Height	Area	Injection Date
STANDAR	8.6	1.2		205.455	5299.7689	10/15/2025 4:45:22 AM
STANDAR	8.6	1.2		205.026	5299.6007	10/15/2025 5:26:40 AM
STANDAR	8.6	1.2		205.786	5300.5496	10/15/2025 6:07:56 AM
STANDAR	8.6	1.2		205.109	5297.9019	10/15/2025 6:49:13 AM
STANDAR	8.6	1.2		205.105	5298.9155	10/15/2025 7:30:30 AM
				Mean	5298.3473	
				Std Dev.	0.9954	
				%RSD	0.0188	

Cross Sequence Summary Report



Agilent

D:\CDSProjects\Oktober 2025\Results\VMA Methisoprinol Kadar\141025_VMA
Presisi 2 Methisoprinol Kadar\rsilt\2025-10-15 08-51-51+07-00-18.dx

P1-A5

1 of 1

Injection volume: 20.0 μ L

Acq. operator: scientist

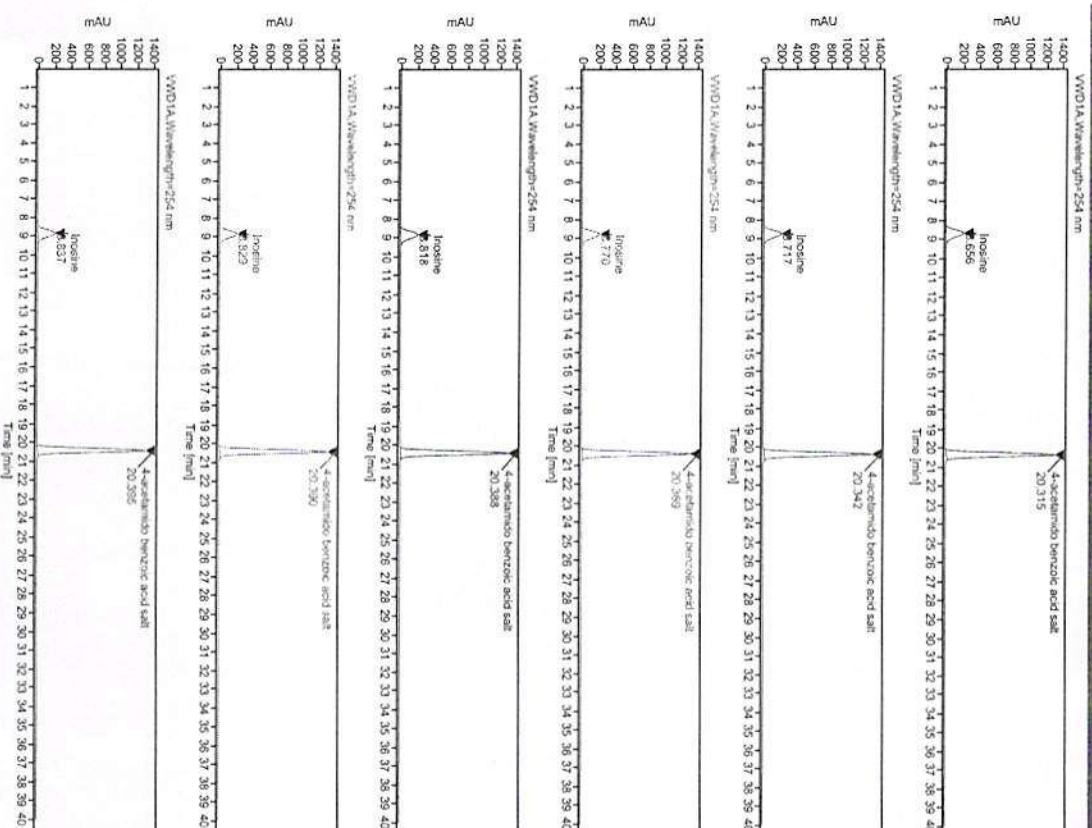
Column Length	150.0 mm
---------------	----------

Column Diameter 4.6 mm

Particle Size 5.0 μm

Name	RT	Tail Factor	Residual	Height	Area	Injection Date
PRESISI ANTARA 2	20.3	1.0	21.68462	1304.417	18948.0351	10/15/2025 8:53:00 AM
PRESISI ANTARA 2	20.3	1.0	21.51107	1306.161	19000.0530	10/15/2025 9:34:15 AM
PRESISI ANTARA 2	20.4	1.0	21.45006	1307.695	19097.6735	10/15/2025 10:15:30 AM
PRESISI ANTARA 2	20.4	1.0	21.39174	1304.684	19085.5239	10/15/2025 10:56:47 AM
PRESISI ANTARA 2	20.4	1.0	21.34869	1306.187	19059.9266	10/15/2025 11:38:04 AM
PRESISI ANTARA 2	20.4	1.0	21.28436	1303.196	19060.6579	10/15/2025 12:19:20 PM
				Mean	18038.6783	
				Std Dev.	54.5297	
				%MSD	0.2864	

Name	RT	Tail Factor	Resolution	Height	Area	Injection Date
PREISI ANTARA 2	8.7	1.1		209.485	5297.9736	10/15/2025 8:53:00 AM
PREISI ANTARA 2	8.7	1.1		207.249	5293.4996	10/15/2025 9:34:15 AM
PREISI ANTARA 2	8.8	1.2		206.592	5248.5595	10/15/2025 10:15:30 AM
PREISI ANTARA 2	8.8	1.1		205.927	5233.5045	10/15/2025 10:56:47 AM
PREISI ANTARA 2	8.8	1.1		206.533	5263.5953	10/15/2025 11:38:04 AM
PREISI ANTARA 2	8.8	1.2		206.072	5229.9287	10/15/2025 12:19:20 PM
				Mean	5267.8452	
				Std.Dev.	29.4837	
				%RSD	0.5608	



DATA PENIMBANGAN

Nama Bahan Baku : Methisoprinol
 No. LSA : B4503760
 Pengujian : Fase Gerak

ktzpo₄
 AM2015173 426

14-Oct-2025 16:43
 Sartorius

Mod. BCE224I-1S
 Ser. no. 45007949
 APC 01-76-05.06.01
 BAC 00-59-05.06.01
 ID PI-AD-T8G-065

N + 5300.0 mg

14-Oct-2025 16:43
 Name: SKA
 14 Oct 2025

Date & Time 14-Oct-2025
 18:43:03

Sample ID Dapar pH 3.5

Comment

Result status

OK

Method ID pH method

Measurement type

pH

Sensor Name Expert+Pico124

Measurement result

3.49 pH

mV 210.2 mV

Temperature 24.3 °C(75.7 °F)

End point Manual (244 seconds)

Stable status

No(Strict)

Signature SKA
 14 Oct 2025

Dilakukan Oleh:	Diperiksa Oleh:
SKA 14 Oct 2025	4 ^{03/25} PAB

DATA PENIMBANGAN

Nama Bahan Baku : Methisoprinol
No. LSA : B4503760
Pengujian : presisi Antara 2

B4503760

14-Oct-2025 20:30

Sartorius

Mod. BCE224I-1S

Ser. no. 45007949

APC 01-76-05.06.01

BAC 00-59-05.06.01

ID PI-AD-TBG-065

Comp01+ 25.0 mg

Comp02+ 25.0 mg

Comp03+ 25.0 mg

Comp04+ 25.0 mg

Comp05+ 25.0 mg

Comp06+ 25.0 mg

n 6

x + 25.00 mg

s 0.00 mg

sRel 0.00 %

Sum + 150.0 mg

Min + 25.0 mg

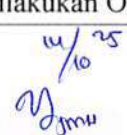
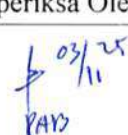
Max + 25.0 mg

Diff 0.0 mg

14-Oct-2025 20:30

Name: Jeth



Dilakukan Oleh:	Diperiksa Oleh:
 14/10/25 JSM	 03/11/25 PAR

Lampiran 8 Protap No. PG-AD-116-00 (LaboratoryWorksheetValidasi Metode Analisis Bahan Baku)

Laboratory Worksheet

PROSEDUR VALIDASI METODE ANALISIS BAHAN BAKU

Nama zataktif : *Methisoprinol*

Tanggal Analisis : *19 Oktober 2025*

Andev Scientist : *Jelly*

Parameter : UKS, Spesifisitas, Presisian antara 2.

1. INFORMASI STANDAR DAN SAMPEL

Reference Standard	Nama	<i>Methisoprinol</i>
	No. Batch/Lot	<i>AB0122678</i>
	Manufacturing Date	<i>na</i>
	Expiry Date	<i>current lot</i>
	Manufacturer	<i>BPF1</i>
Reference Standard	Nama	<i>Inosine</i>
	No. Batch/Lot	<i>2023-CP0-018</i>
	Manufacturing Date	<i>26 Januari 2023</i>
	Expiry Date	<i>24 Januari 2027</i>
	Manufacturer	<i>TRC</i>
Sampel	Nama	<i>Methisoprinol</i>
	No. Batch/Lot	<i>MTP250225</i>
	Manufacturing Date	
	Expiry Date	<i>30 April 2028</i>
	Manufacturer	<i>Unibios</i>

2. REFERENSI PROSEDUR METODE ANALISIS

Pengujian	Referensi
Kadar Bahan Baku <i>Methisoprinol</i>	<i>In House Method Mengacu Analytical Method of Manufacturer Tahun 2023 (ABC Farmaceutici)</i>

3. PARAMETER PENGUJIAN

REAGEN					
Nama	Grade	Manufacturer	No. Batch/Lot	Expiry Date	Open Date
<i>Potassium dihydrogen phosphate</i>	<i>Analysis</i>	<i>Merck</i>	<i>AM2015173476</i>	<i>30 Nov 2028</i>	<i>30 Sep 2025</i>
<i>Ortho phosphoric acid 80%</i>	<i>Analysis</i>	<i>Merck</i>	<i>F53 202673110</i>	<i>31 Agu 2027</i>	<i>28 Apr 2025</i>

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Methanol	LC	Merck	J1382207448	30 Nov 2027	14 Okt 2025
Purified water	LC	fresh			

INSTRUMENTASI			
Nama Instrumen	Brand	No. Alat	Tanggal Batas Kalibrasi
HPLC	Agilent Infinity II	PI-AD-HPC-109	09 & 1 2026
Timbangan	Sartorius BCE2241-15	PI-AD-TBG-065	10 Sep 2026
pH Meter	Mettler Toledo	PI-AD-PHM-102-E	30 Jan 2026
Sonikator	Power Sonic 420	PI-AD-UTR-056	NA
Arium	Sartorius Arium Comfort	PI-AD-ARC-049	NA

SISTEM INSTRUMENTASI				
Parameter				Aktual
Instrumen	HPLC Agilent Infinity II			Sesuai/Tidak* Jika Tidak :
Kolom	L1; 4,6 mm x 15 cm (5µm)			Brand kolom : <i>Rumospher</i> Serial number : <i>310767</i> Sesuai/Tidak* Jika Tidak :
Fase Gerak	Waktu (menit)	Larutan Fase Gerak A (%)	Larutan Metanol (%)	Sesuai/Tidak* Jika Tidak :
	5	95	5	
	10	90	10	
	25	40	60	
	32	40	60	
	35	95	5	
	40	95	5	

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

Pelarut	Purified water	Sesuai/Tidak* Jika Tidak
Suhu Kolom	25 °C	Sesuai/Tidak* Jika Tidak
Suhu auto sampler	20 °C	Sesuai/Tidak* Jika Tidak
Laju Alir	1 mL/menit	Sesuai/Tidak* Jika Tidak :
Detektor	254 nm	Sesuai/Tidak* Jika Tidak :
Volume Injeksi	20µL	Sesuai/Tidak* Jika Tidak :
Retention time	4 acetamido benzoic acid : 20,3 menit Inosine : 8,6 menit	
Runtime/End time	40 menit	Sesuai/Tidak* Jika Tidak :

*) Lingkari yang sesuai

Jika tidak sesuai, berikan keterangan aktual pengerjaan

PREPARASI LARUTAN											
Prosedur	Aktual										
Fase Gerak A 1. Timbang 2.65 g <i>potassium dihydrogen phosphate</i> masukkan ke dalam <i>beaker glass</i> 1000 mL. 2. Larutkan dan encerkan dengan 1000 mL air, aduk hingga homogen. 3. Atur pH larutan dengan penambahan <i>ortho phosphoric acid</i> 80% hingga dicapai pH 3.5. Saring dan <i>degass</i> .	<table border="1"> <tr> <td colspan="2">Fase Gerak A</td></tr> <tr> <td><i>Potassium Dihydrogen Phosphate</i></td><td>5300 mg</td></tr> <tr> <td><i>Purified water</i></td><td>2000 mL</td></tr> <tr> <td><i>ortho phosphoric acid</i> 80%</td><td>5 Tetes</td></tr> <tr> <td>pH larutan</td><td>3.5</td></tr> </table>	Fase Gerak A		<i>Potassium Dihydrogen Phosphate</i>	5300 mg	<i>Purified water</i>	2000 mL	<i>ortho phosphoric acid</i> 80%	5 Tetes	pH larutan	3.5
Fase Gerak A											
<i>Potassium Dihydrogen Phosphate</i>	5300 mg										
<i>Purified water</i>	2000 mL										
<i>ortho phosphoric acid</i> 80%	5 Tetes										
pH larutan	3.5										
Fase Gerak B Metanol P	<table border="1"> <tr> <td colspan="2">Analisis (Inisial) : MM</td></tr> <tr> <td>TTD</td><td>Tgl Analisis</td></tr> <tr> <td>ny</td><td>14/10/25</td></tr> </table>	Analisis (Inisial) : MM		TTD	Tgl Analisis	ny	14/10/25				
Analisis (Inisial) : MM											
TTD	Tgl Analisis										
ny	14/10/25										
Pelarut <i>Purified water.</i>	Diperiksa oleh : 03/11/25 HHS										

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

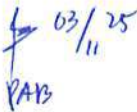
Laboratory Worksheet

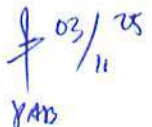
SPESIFISITAS							
Prosedur	Aktual						
Larutan Fase Gerak Suntikkan 20 µL larutan Fase gerak yang sudah disaring dengan <i>membrane filter</i> 0,45 µm ke dalam alat HPLC yang telah dikondisikan. Larutan Pelarut Suntikkan 20µL larutan Pelarut yang sudah disaring dengan <i>membrane filter</i> 0,45 µm ke dalam alat HPLC yang telah dikondisikan.	<table border="1"> <tr> <td colspan="2">Analisis (Inisial): JM</td></tr> <tr> <td>TTD</td><td>Tgl Analisis</td></tr> <tr> <td>JM</td><td>14/10/25</td></tr> </table> Diperiksa oleh : 03/25 11 PAB	Analisis (Inisial): JM		TTD	Tgl Analisis	JM	14/10/25
Analisis (Inisial): JM							
TTD	Tgl Analisis						
JM	14/10/25						

UJI KESESUAIAN SISTEM																			
Prosedur	Aktual																		
Larutan Identifikasi Inosine 1. Timbang 120,3 mg Inosine RS masukkan ke dalam labu ukur 50 mL. 2. Larutkan dengan 25 mL <i>methanol</i>, kocok hingga larut. 3. Tambahkan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen ($C_{Inosine RS} = 2,406 \text{ mg/mL}$). 4. Pipet 1,0 mL Larutan masukkan ke dalam labu ukur 20 mL. 5. Tambahkan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen. 6. Saring larutan menggunakan <i>membrane filter</i> 0,45 µm ke vial LC ($C_{Inosine RS} = 0,1203 \text{ mg/mL}$). Larutan Standar 1. Timbang 10 mg Methisoprinol RS masukkan ke dalam labu ukur 20 mL.	<table border="1"> <tr> <td colspan="2">Identifikasi Inosine</td></tr> <tr> <td>Bobot Inosine RS</td><td>NA mg</td></tr> <tr> <td>Volume Methanol</td><td>NA mL</td></tr> <tr> <td>Volume Labu</td><td>NA mL</td></tr> <tr> <td>Volume Pemipetan</td><td>1 mL</td></tr> <tr> <td>Volume Labu</td><td>20 mL</td></tr> </table> menggunakan larutan stok 29 Sep 2025, dilatikan oleh SKA, konsentrasi 2,406 mg/mL 14/10/25 JM <table border="1"> <tr> <td colspan="2">Larutan Standar</td></tr> <tr> <td>Bobot Methisoprinol RS</td><td>NA mg</td></tr> <tr> <td>Volume Labu</td><td>NA mL</td></tr> </table>	Identifikasi Inosine		Bobot Inosine RS	NA mg	Volume Methanol	NA mL	Volume Labu	NA mL	Volume Pemipetan	1 mL	Volume Labu	20 mL	Larutan Standar		Bobot Methisoprinol RS	NA mg	Volume Labu	NA mL
Identifikasi Inosine																			
Bobot Inosine RS	NA mg																		
Volume Methanol	NA mL																		
Volume Labu	NA mL																		
Volume Pemipetan	1 mL																		
Volume Labu	20 mL																		
Larutan Standar																			
Bobot Methisoprinol RS	NA mg																		
Volume Labu	NA mL																		

Lampiran 8 Protap No. PG-AD-116-00 (Laboratory Worksheet Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

2. Larutkan dengan 10,0 mL <i>purified water</i> , kocok hingga larut. 3. Tambahkan dengan <i>purified water</i> hingga tanda batas kemudian kocok hingga homogen. 4. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$).	menggunakan katan stok 06 okt 2025, ditantkan oleh JMH, konsentrasi 0,5 mg/mL 14/10/25 JMH	
	Analisis (Inisial) : JMH	
	TTD	Tgl Analisis
		14/10/25
Diperiksa oleh :		
 03/11/25 YAB		

PRESISI ANTARA 1																							
Prosedur	Aktual																						
Larutan Standar Lakukan sesuai prosedur Uji Kesesuaian Sistem. Presisi Antara 1 1. Timbang 25 mg sampel Methisoprinol , masukkan ke dalam labu ukur 50 mL. 2. Larutkan dengan 25 mL <i>purified water</i> , kocok hingga larut. 3. Tambahkan <i>purified water</i> hingga tanda batas kemudian homogenkan. 4. Saring larutan menggunakan <i>membrane filter</i> 0,45µm ke vial LC. ($C_{Inosine} = 0,5 \text{ mg/mL}$; $C_{\text{acetamido benzoic acid salt}} = 0,5 \text{ mg/mL}$).	<table border="1"> <tr> <th colspan="2">Presisi Antara 1</th> </tr> <tr> <td>Bobot Sampel 1</td> <td>.....25..... mg</td> </tr> <tr> <td>Bobot Sampel 2</td> <td>.....25..... mg</td> </tr> <tr> <td>Bobot Sampel 3</td> <td>.....25..... mg</td> </tr> <tr> <td>Bobot Sampel 4</td> <td>.....25..... mg</td> </tr> <tr> <td>Bobot Sampel 5</td> <td>.....25..... mg</td> </tr> <tr> <td>Bobot Sampel 6</td> <td>.....25..... mg</td> </tr> <tr> <td>Volume Labu</td> <td>.....50..... mL</td> </tr> </table> <table border="1"> <tr> <td colspan="2"> Analisis (Inisial) : JMH </td> </tr> <tr> <td>TTD</td> <td>Tgl Analisis</td> </tr> <tr> <td>  </td> <td> 14/10/25 </td> </tr> </table> Diperiksa oleh :  03/11/25 YAB	Presisi Antara 1		Bobot Sampel 1	25..... mg	Bobot Sampel 2	25..... mg	Bobot Sampel 3	25..... mg	Bobot Sampel 4	25..... mg	Bobot Sampel 5	25..... mg	Bobot Sampel 6	25..... mg	Volume Labu	50..... mL	Analisis (Inisial) : JMH		TTD	Tgl Analisis		14/10/25
Presisi Antara 1																							
Bobot Sampel 1	25..... mg																						
Bobot Sampel 2	25..... mg																						
Bobot Sampel 3	25..... mg																						
Bobot Sampel 4	25..... mg																						
Bobot Sampel 5	25..... mg																						
Bobot Sampel 6	25..... mg																						
Volume Labu	50..... mL																						
Analisis (Inisial) : JMH																							
TTD	Tgl Analisis																						
	14/10/25																						

Lampiran 8 Protap No. PG-AD-116-00 (*Laboratory Worksheet* Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

SEQUENCE DAN KRITERIA PENERIMAAN

A. SEQUENCE

Komponen	Replikasi Preparasi	Replikasi Injeksi
Spesifisitas Pelarut	1	2
Spesifitas Fase Gerak	1	2
Uji Kesesuaian Sistem dan Larutan Standar	1	5
Presisi antara 1	6	1

B. KRITERIA PENERIMAAN

Komponen	Kriteria Penerimaan
Uji Kesesuaian Sistem dan Larutan Standar	% RSD <i>Inosine</i> dan <i>4-acetamido benzoic acid salt</i> : $\leq 1,04\%$
	<i>Tailing Factor Inosine</i> dan <i>4-acetamido benzoic acid salt</i> : 0,8 – 1,5
Spesifisitas Pelarut	Tidak ada Interferensi dari pelarut
Spesifisitas Fase gerak	Tidak ada Interferensi dari fase gerak
Presisi Rpitabilitas	RSD rata-rata <i>recovery</i> : $\leq 2,0\%$
Presisi antara 2	Kadar <i>Inosine</i> : 95,0 – 105,0%, <i>on dried basis</i>
	Kadar <i>4-acetamido benzoic acid salt</i> : 95,0 – 105,0%, <i>on dried basis</i>
	% RSD Kadar <i>Inosine</i> dan <i>4-acetamido benzoic acid salt</i> antar analisis : $\leq 2,0\%$

RUMUS PERHITUNGAN

1. Presisi

% kadar *Inosine* dan *4-acetamido benzoic acid salt* dengan rumus:

$$\% \text{ Kadar} = \frac{ru}{rs} \times \frac{Ws}{Wu} \times \frac{P}{(100 - KF)} \times \frac{Du}{Ds} \times 100$$

Keterangan :

ru = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan sampel

rs = Respon area *peak Inosine* dan *4-acetamido benzoic acid salt* dari larutan standar

Ws = Bobot penimbangan dari larutan standar (mg)

Wu = Bobot penimbangan dari larutan sampel (mg)

Lampiran 8 Protap No. PG-AD-116-00 (*Laboratory Worksheet* Validasi Metode Analisis Bahan Baku)

Laboratory Worksheet

P	= Potensi Methisoprinol RS (%)
Du	= Faktor pengenceran dari larutan sampel
Ds	= Faktor pengenceran dari larutan standar
KF	= Kadar air sampel