

	PROTAP Cara Menelusuri Fitur Audit Trail Alat HPLC 7 Agilent 1260 Series	No : PPB 128
		Revisi : 00
		Berlaku : 20 JUL 2020
		Paraf : 

1 Tujuan

Agar setiap pemakaian menggunakan cara yang benar, sehingga didapatkan hasil analisa yang akurat dan kerusakan alat karena salah pengoperasian dapat dihindari.

2 Cakupan

Protap ini sebagai panduan untuk menelusuri fitur audit *trail* alat HPLC Agilent 7 di laboratorium pengawasan mutu.

3 Penanggung Jawab

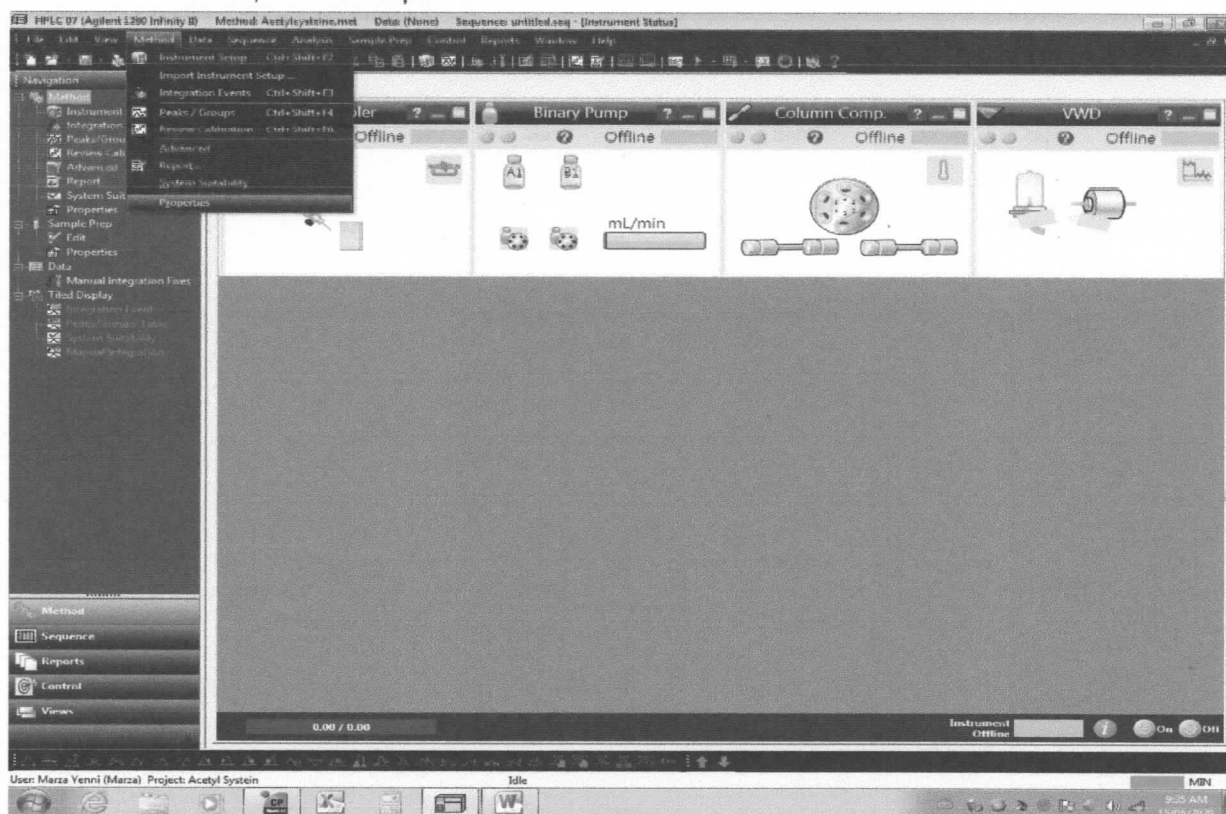
Penanggung jawab protap ini adalah Supervisor Pengujian Bahan Awal dan Bahan Kemas.

4 Definisi

Audit *trail* HPLC adalah suatu fitur pada program HPLC yang dapat menyimpan semua aktifitas user dan secara *default* akan mencatat waktu, user, data yang diakses, kegiatan menambah, mengubah dan menghapus yang dilakukan oleh setiap user dalam sistem HPLC.

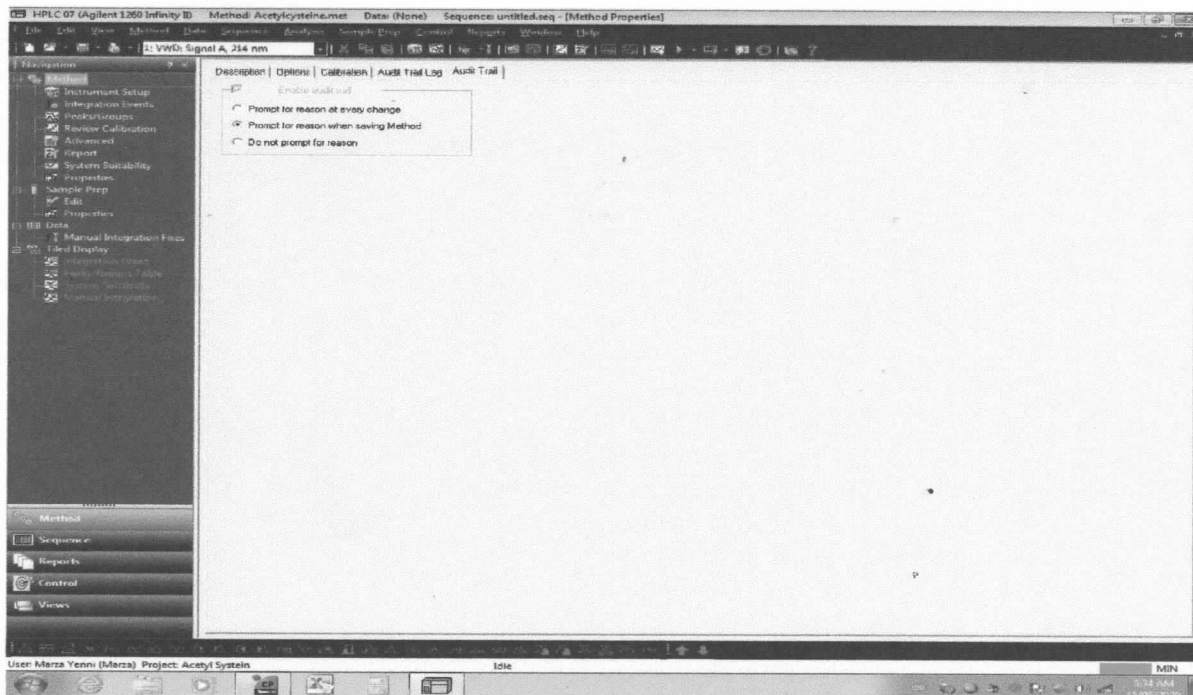
5 Prosedur

- 5.1 Pada tampilan desktop komputer masuk keaplikasi OpenLAB Control Panel.
- 5.2 User masuk menggunakan username dan password masing – masing.
- 5.3 Kemudian klik project pada pilihan panel sebelah kiri.
- 5.4 Pilih Instrument pada pilihan panel sebelah kiri, kemudian klik *Browse* untuk memilih *Project* yang telah dibuat.
- 5.5 Klik *Launch* untuk membuka sistem *Online* HPLC.
- 5.6 Pilih *method*, lalu klik *Properties*



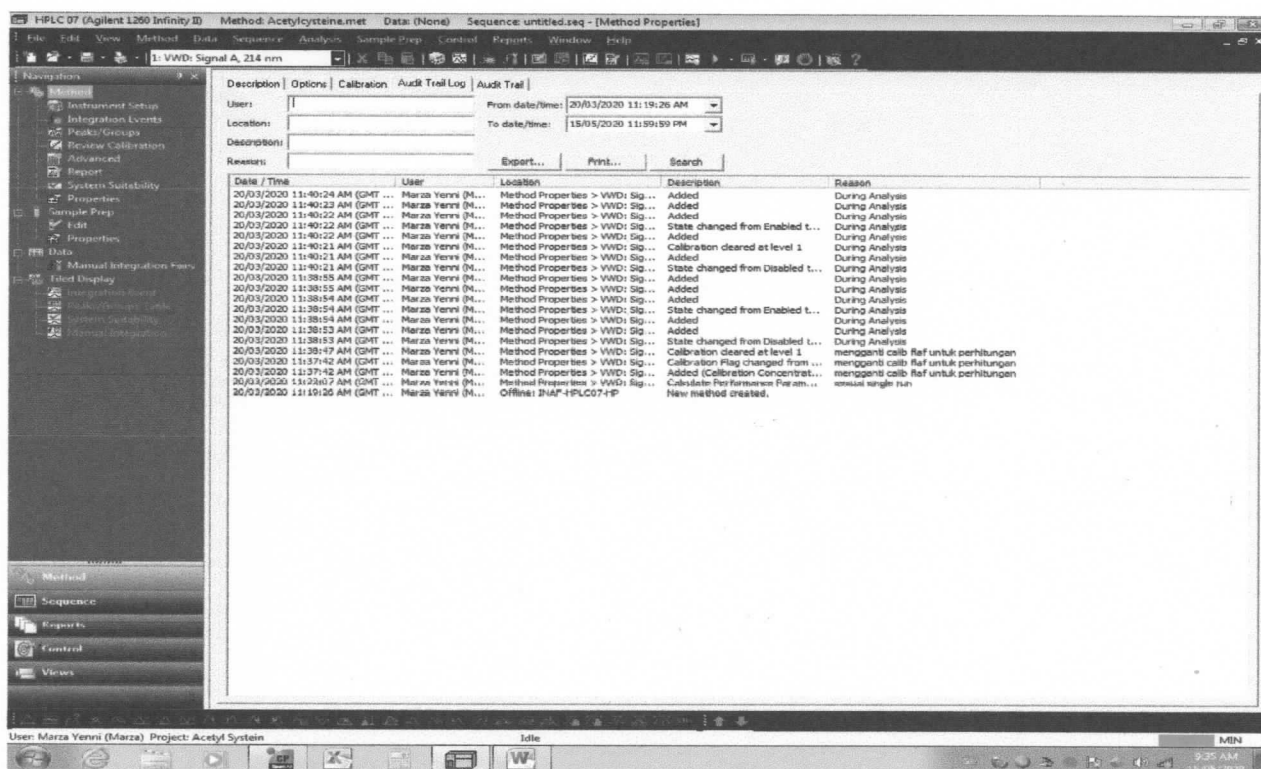
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5.7 Lalu pilih *audit trail*, klik *Enable audit trail* dan klik *Prompt for reason when saving Method*.



5.8 Untuk melihat *activity log audit trail*, klik *Audit Trail Log*, lalu pilih tanggal untuk melihat data *audit trail* yang diinginkan.

5.9 Setelah diperoleh data yang diinginkan, hasil dapat diprint dengan cara klik *Print*.



5.10 Pemeriksaan tanggal, jam atau record time di HPLC dapat dilihat di *Audit Trail Log*



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The screenshot shows the 'Audit Trail Log' window in the HPLC software. The window title is 'HPLC 07 (Agilent 1260 Infinity II) (Offline) Method: Acetylcysteine.met Data: (None) Sequence: untitled.seq - [Method Properties]'. The main area displays a table of audit trail events. The 'Date / Time' column is circled in red. The table contains the following data:


Date / Time	User	Location	Description	Reason
20/03/2020 11:40:24 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:40:23 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:40:22 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... State changed from Enabled t...	During Analysis
20/03/2020 11:40:22 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:40:21 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Calibration cleared at level 1	During Analysis
20/03/2020 11:40:21 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:38:55 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... State changed from Disabled t...	During Analysis
20/03/2020 11:38:55 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:38:54 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... State changed from Enabled t...	During Analysis
20/03/2020 11:38:54 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:38:53 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Calibration cleared at level 1	During Analysis
20/03/2020 11:38:53 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added	During Analysis
20/03/2020 11:38:47 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... State changed from Disabled t...	During Analysis
20/03/2020 11:37:42 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Calibration flag changed from ...	mengganti calib flaf untuk perhitungan
20/03/2020 11:37:42 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Added (Calibration Concentrat...	mengganti calib flaf untuk perhitungan
20/03/2020 11:33:07 AM (GMT ...)	Marza Yenni (M...		Method Properties > VWD: Sig... Calculate Performance Param...	sesuai single run
20/03/2020 11:19:26 AM (GMT ...)	Marza Yenni (M...		Offline: INAF-HPLC07HP	New method created.

5.11 Pemeriksaan kesesuaian metode analisa, File → Open Result Set → Pilih Result Sequence

The screenshot shows the 'Result Review Mode' window in the HPLC software. The window title is 'HPLC 07 (Agilent 1260 Infinity II) (Offline) Method: Acetylcysteine.met Data: WS_Acetylcysteine_20059N12_it_Rep1.dat Sequence: Acetylcysteine.w'. The main area displays a chromatogram with a single sharp peak at approximately 3.8 minutes. Below the chromatogram is a 'Result Sequence' table. The 'Method' column is circled in red. The table contains the following data:

Run #	Level	Conn	Custom	Recipe	Vial	Volume	Sample	Sample ID	Method	Master Folder	Filename	Sample Amt.
1	0	n/a	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep1.dat			
2	1	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep2.dat				
3	1	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep3.dat				
4	1	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep4.dat				
5	1	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep5.dat				
6	0	n/a	Unconfigur...	1	P1-A1	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_Rep6.dat			
7	0	n/a	Unconfigur...	1	P1-A2	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_001.dat			25.1
8	0	n/a	Unconfigur...	1	P1-A3	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_002.dat			25.1
9	0	n/a	Unconfigur...	1	P1-A4	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_003.dat			25
10	0	n/a	Unconfigur...	1	P1-A5	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_004.dat			25
11	0	n/a	Unconfigur...	1	P1-A6	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_005.dat			25.1
12	0	n/a	Unconfigur...	1	P1-A7	Use Method	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_it_006.dat			25.1

5.12 Pemeriksaan urutan pengujian sampel. File → Open Sequence → Pilih Sequence



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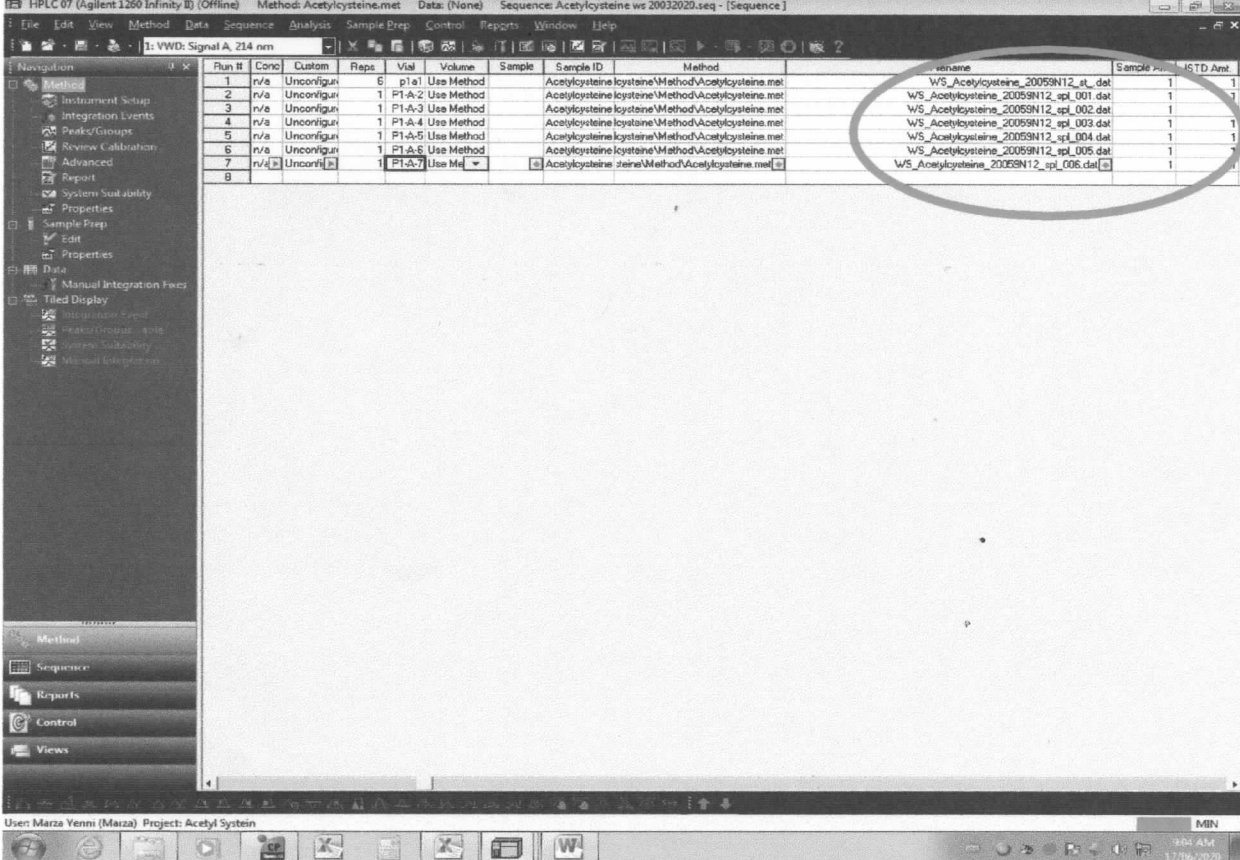
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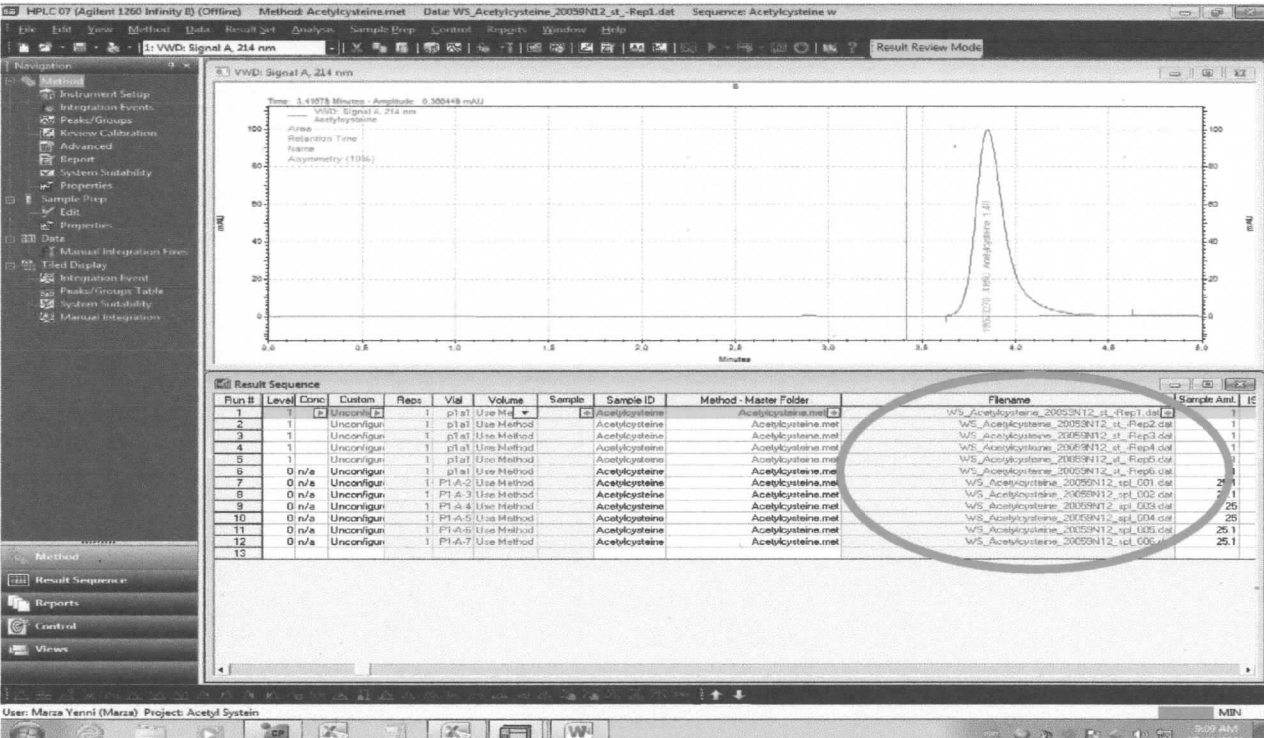
Berlaku : 20 JUL 2020

Paraf : *[Signature]*



Run #	Conc	Custom	Reps	Vial	Volume	Sample	Sample ID	Method	Filename	Sample Amt	STD Amt
1	n/a	Unconfig	6	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st.dat	1	1
2	n/a	Unconfig	1	P1-A-2	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_001.dat	1	1
3	n/a	Unconfig	1	P1-A-3	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_002.dat	1	1
4	n/a	Unconfig	1	P1-A-4	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_003.dat	1	1
5	n/a	Unconfig	1	P1-A-5	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_004.dat	1	1
6	n/a	Unconfig	1	P1-A-6	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_005.dat	1	1
7	n/a	Unconfig	1	P1-A-7	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_006.dat	1	1
8	n/a	Unconfig	1	P1-A-7	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_006.dat	1	1

5.13 Pemeriksaan jejak arsip data, File → Open Result Set → Pilih Result Sequence



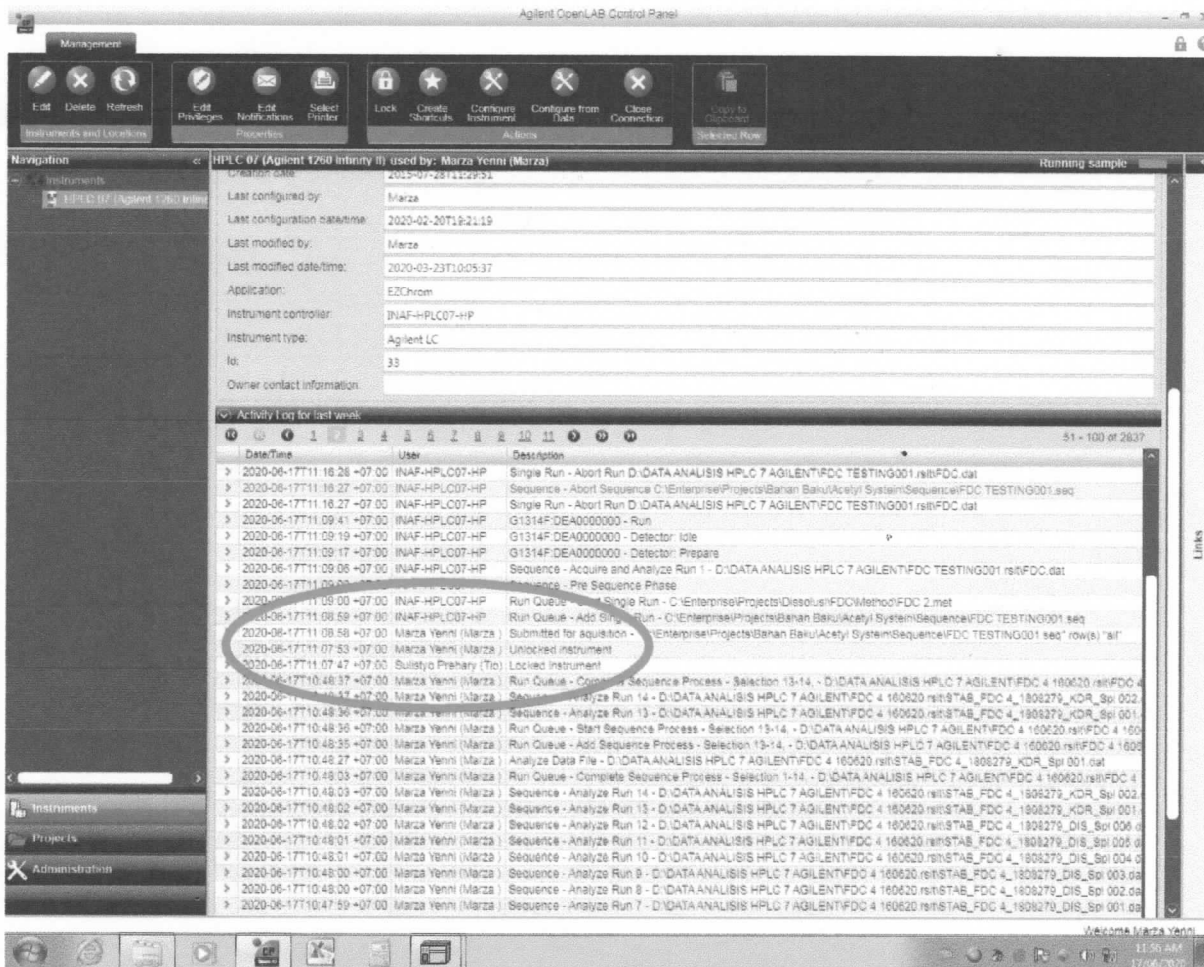
Time: 3.4978 Minutes, Amplitude: 0.358448 mAU
 VWD: Signal A, 214 nm
 Acetylcysteine

Area: 100
 Retention Time: 3.4978
 Asymmetry (10%): 1.00

Run #	Level	Conc	Custom	Reps	Vial	Volume	Sample	Sample ID	Method - Master Folder	Filename	Sample Amt	IE
1	1	n/a	Unconfig	6	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep1.dat	1	1
2	1	n/a	Unconfig	1	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep2.dat	1	1
3	1	n/a	Unconfig	1	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep3.dat	1	1
4	1	n/a	Unconfig	1	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep4.dat	1	1
5	1	n/a	Unconfig	1	P1-A-1	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep5.dat	1	1
6	0	n/a	Unconfig	1	P1-A-2	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_st_Rep6.dat	1	1
7	0	n/a	Unconfig	1	P1-A-2	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_001.dat	25	1
8	0	n/a	Unconfig	1	P1-A-3	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_002.dat	25	1
9	0	n/a	Unconfig	1	P1-A-4	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_003.dat	25	1
10	0	n/a	Unconfig	1	P1-A-5	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_004.dat	25	1
11	0	n/a	Unconfig	1	P1-A-6	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_005.dat	25	1
12	0	n/a	Unconfig	1	P1-A-7	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_006.dat	25	1
13	0	n/a	Unconfig	1	P1-A-7	Use Method	Acetylcysteine	Acetylcysteine	Acetylcysteine.met	WS_Acetylcysteine_20059N12_spl_006.dat	25	1

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5.14 Pemeriksaan jejak login dan logout dapat dilihat *Activity Log* pada *Agilent OpenLAB Control Panel*



6 **Pustaka**

Buku panduan penggunaan Alat HPLC Agilent 1260 Infinity.

7 **Catatan Perubahan**


Rev	Berlaku	Perubahan
00	20 JUL 2020	Dokumen terbitan pertama.

8 **Tinjauan Ulang**





Protap ini akan ditinjau ulang setiap 2 tahun (atau kurang jika perlu) oleh Manajer Pengawasan Mutu dan Manajer Pemastian Mutu.

9 **Distribusi**

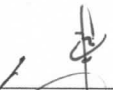

- 9.1. Bidang Pengawasan Mutu
- 9.2. Bidang Pemastian Mutu

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10 Pengesahan

Keterangan	Jabatan	Kode Bidang	Tanda tangan	Tanggal
Disusun oleh	Supervisor Pengujian Bahan Awal dan Bahan Kemasan	AM	Ub 	15 JUL 2020
Diperiksa oleh	Asman Pengujian Bahan Awal dan Produk	AM		15 JUL 2020
Disetujui oleh	Manajer Pengawasan Mutu	AM		15 JUL 2020
	Manajer Pemastian Mutu	PM		15 JUL 2020

11 Tinjauan

No.	Peninjau	Tgl. Tinjauan	Tanda tangan	Rekomendasi
1.	Manajer Pengawasan Mutu	25 Jul 22		Protap masih sesuai
	Manajer Pemastian Mutu	04 Agv 2020		masih sesuai
2.	Manajer Pengawasan Mutu			
	Manajer Pemastian Mutu			



DAFTAR HADIR

No : F-WM-01-08

Revisi : 01

Berlaku : 23 Jul 2018

Hal. : 1 / 1

Tanggal : 16 Juli 2020

Waktu : 08.00 - selesai

Tempat : lab Pengawasan Mutu

Agenda : Cara Pengoperasian Alat HPLC 7 Agilent 1260 Series & Cara menelusuri Fitur Audit
PPB 085 (rev:03) , PPB 128 (rev:00) Trial alat HPLC 7, 1260 Series

No	Nama	Instansi / Bidang	Alamat Email	No. Telepon	Tanda Tangan
1.	Indah Hukimiyanti	QC		238	b.
2.	Sulistio	QC		--	s
3.	Abdul	QC		116	X
4.	Yuliana	QC		203	Y
5.	Yuso	QC		203	X
6.	Jessica	QC		238	2
7.	Mirakurnia	QC		116	Y
8.	Aurika	QC		116	Y
9.	RURI	QC		116	Ri
10.	Septi Yanti	QC		203	X
11.	Anandhi	QC		203	J
12.	Riska	QC		203	B
13.	Fanny	QC		203	F
14.	Resha	QC		233	184
15.	Lisa W.	QC		203	W
16.	Dinda	QC		203	A
17.	Marta Yenni	QC		203	Y