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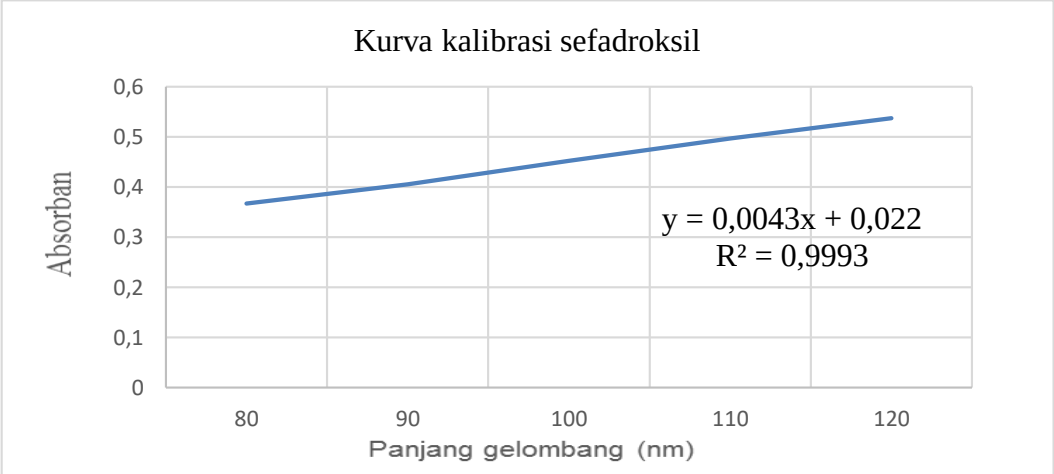
LAMPIRAN 1

LINEARITAS

Tabel V.4
Data Hasil Uji Linearitas

Konsentrasi (ppm)	Absorban
80	0,367
90	0,4054
100	0,4519
110	0,4955
120	0,5366
Persamaan baku	Y = 0,0043x + 0,022
Simpangan baku residual (Sy)	0,000019
Standar deviasi fungsi (Sx_0)	0,58
Koefisien variasi fungsi (Vx_0)	0,58%



Gambar V.3 Kurva Kalibrasi Sefadroksil

LAMPIRAN 1
(LANJUTAN)

Konsentrasi teoritis(ppm)	Serapan pada λ 400 nm terukur (y)	konsentrasi terukur	Serapan pada λ 400 nm teoritis (ŷ)	$(y - \hat{y})$
80	0,367	80,233	0,366	0,000001
90	0,405	90,069	0,409	0,000016
100	0,452	100	0,452	0
110	0,496	110,232	0,495	0,000001
120	0,537	119,767	0,538	0,000001
		$\bar{x}$ =99,86		0,000019

Perhitungan simpangan baku residual (Sy)

$$Sy = \sqrt{\frac{\sum(y - \hat{y})^2}{n - 2}}$$

$$Sy = \sqrt{\frac{0,000019}{3}}$$

$$Sy = 0,0025$$

LAMPIRAN 1
(LANJUTAN)

Perhitungan standar deviasi (Sx_0)

$$Sx_0 = \frac{Sy}{b}$$

$$Sx_0 = \frac{0{,}0025}{0{,}0043}$$

$$Sx_0 = 0{,}58$$

Perhitungan koefisien variasi dari fungsi (Vx_0)

$$Vx_0 = \frac{Sx_0}{x}$$

$$Vx_0 = \frac{0{,}58}{99{,}86} = 0{,}0058$$

$$Vx_0 = 0{,}58\ \%$$

LAMPIRAN 2
UJI PRESISI

Tabel V.5
Hasil Uji Presisi Larutan Standar Sefadroksil

Konsentrasi (ppm)	**Absorban**	**X**	**x-$\bar{x}$**	**$(x-\bar{x})^2$**
80	0,3613	78,91	2,076667	4,312544
80	0,3484	75,91	-0,92333	0,852544
80	0,3525	76,86	0,026667	0,000711
80	0,3466	75,49	-1,34333	1,804544
80	0,3487	75,97	-0,86333	0,745344
80	0,3568	77,86	1,026667	1,054044
Jumlah		461		8,769733
Rata-rata		76,8333		
SD		1,32436		
%*RSD*				1,723687
% CV Horwitz				8,32
0.67 x % CV Horwitz				5,55
HorRat				0,31
Ketelitian alat				99,98276

LAMPIRAN 2
(LANJUTAN)

$$SD = \sqrt{\frac{\sum(x-\bar{x})^2}{n-1}}$$

$$SD = \sqrt{\frac{8,77}{6-1}}$$

SD = 1,32

$$\%RSD = \frac{SD}{x} x\ 100\%$$

$$\%RSD = \frac{1,32}{76,83} x\ 100\% = 1,7\%$$

% CV Horwitz $= 2^{1-0,5\log C}$

% CV Horwitz $= 2^{1-0,5\log 76.83x10^{-6}}$

% CV Horwitz = 8,32 %

CV hitung (%) $\leq \frac{2}{3}$ CV Horwitz

CV hitung (%) $\leq$ 5,55 %

$$HorRat = \frac{CV}{CV_{Horwitz}}$$

$$HorRat = \frac{1,7}{5,55}$$

$$HorRat = 0,31$$

$$\%Ketelitian\ alat = 100\% - \frac{SD}{x}$$

$$\%Ketelitian\ alat = 100\% - \frac{1,32}{76,83} = 99,98\ \%$$

LAMPIRAN 3

UJI AKURASI

Tabel V.6
Data Nilai Perolehan Kembali dalam Uji Akurasi

Konsentrasi (ppm)	**Absorban**	**x (ppm)**	***%Recovery***
64	0.2925	62.90698	98.29215
	0.2919	62.76744	98.07413
	0.2939	63.23256	98.80087
Rata-rata			98.38905
80	0.3635	79.88372	99.85465
	0.3666	80.60465	100.7558
	0.3632	79.81395	99.76744
Rata-rata			100.126
96	0.4318	95.76744	99.75775
	0.4239	93.93023	97.84399
	0.4356	96.65116	100.6783
Rata-rata			99.42668

Diperoleh kurva kalibrasi y = bx+a

y = 0,0043x +0,022; r^2=0,9993

$$x = \frac{y - 0.022}{0.0043}$$

LAMPIRAN 3
(LANJUTAN)

sehingga diperoleh,

80%

- $x = \frac{0,2925-0,022}{0,0043} = 62,91$

  $\%recovery = \frac{62,91}{64} = 98,29$

- $x = \frac{0,2919-0,022}{0,0043} = 62,77$

  $\%recovery = \frac{62,77}{64} = 98,07$

- $x = \frac{0,2939-0,022}{0,0043} = 63,23$

  $\%recovery = \frac{63,23}{64} = 98,8$

100%

- $x = \frac{0,3635-0,022}{0,0043} = 79,88$

  $\%recovery = \frac{79,88}{80} = 99,85$

- $x = \frac{0,3666-0,022}{0,0043} = 80,6$

  $\%recovery = \frac{79,88}{80} = 100,76$

- $x = \frac{0,3632-0,022}{0,0043} = 79,81$

  $\%recovery = \frac{80,60}{80} = 99,77$

LAMPIRAN 3
(LANJUTAN)

120%

- $x = \frac{0,4318-0,022}{0,0043} = 95,77$

  $\%recovery = \frac{95,77}{96} = 99,76$

- $x = \frac{0,4239-0,022}{0,0043} = 93,93$

  $\%recovery = \frac{93,93}{96} = 97,84$

- $x = \frac{0,4239-0,022}{0,0043} = 96,65$

  $\%recovery = \frac{96,65}{96} = 100,67$

LAMPIRAN 4

NILAI LOD DAN LOQ

Tabel V.7
Hasil Penentuan Nilai LOD dan LOQ Larutan Sefadroksil

x (ppm)	Y	Yi	y-yi	y-yi
80	0,367	0,366	0,001	0,000001
90	0,405	0,409	-0,004	0,000016
100	0,452	0,452	0	0
110	0,496	0,495	0,001	0,000001
120	0,537	0,538	-0,001	0,000001
Jumlah				0,000019
LOD				1,76 µg/mL
LOQ				5,86 µg/mL

$$SB = \sqrt{\frac{\sum(Y-Yi)^2}{n-2}} =$$

$$SB = \sqrt{\frac{0,000019}{3}}$$

$$SB = 2,52\ X\ 10^{-3}$$

LAMPIRAN 4
(LANJUTAN)

$$LoD = \frac{3\ x\ SB}{b}$$

$$LOD = \frac{3\ x\ 2{,}52\ X\ 10^{-3}}{0{,}0043} = 1{,}76\ \mu g/mL$$

$$LOQ = \frac{10\ x\ 2{,}52\ X\ 10^{-3}}{0{,}0043} = 5{,}86\ \mu g/mL$$

LAMPIRAN 5

PENETAPAN KADAR

Tabel V.8
Hasil Penetapan Kadar Sefadroksil dalam Suspensi

Sampel	Absorban	Konsentrasi diketahui (mg/5mL)	Konsentrasi terukur (µg/mL)	*%Recovery*
Merk "X"	0.3655	125	79.8837	99.8547
	0.3725		81.5116	101.89
	0.3594		78.4651	98.0814
	Rata rata		79.9535	99.9419
Simulasi	0.364	125	79.5349	99.4186
	0.3326		72.2326	90.2907
	0.3701		80.9535	101.192
	Rata rata		77.5736	96.9671

Faktor pengenceran = 312,5x

Kadar obat (mg) = Faktor pengenceran x rata rata x volume larutan

Kadar obat merk “x”= 312,5 x 79,95 x 0,005

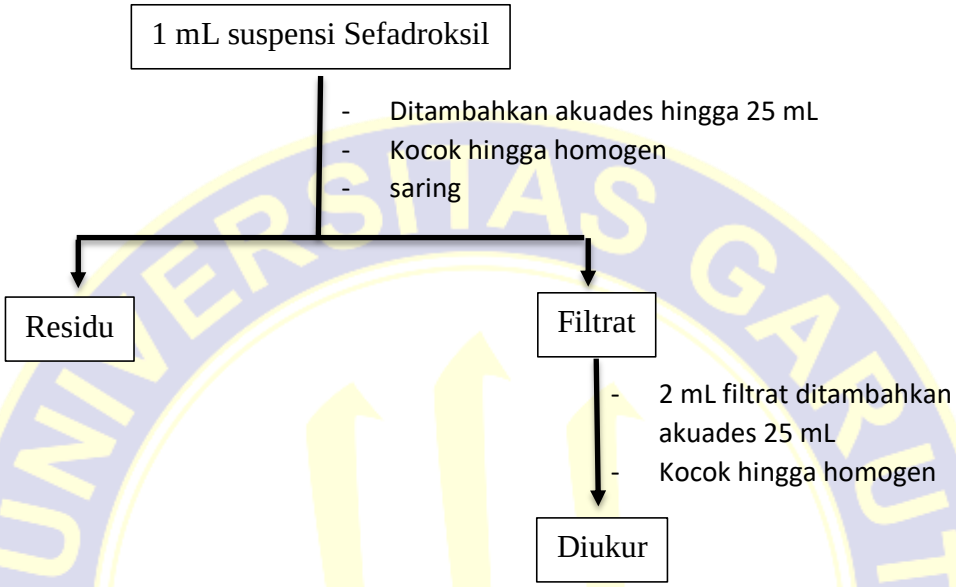
Kadar obat merk “x” =124,92 mg/5mL

Kadar obat simulasi = 312,5 x 77,57 x 0,005

Kadar obat simulasi = 121,20 mg/5mL

LAMPIRAN 6

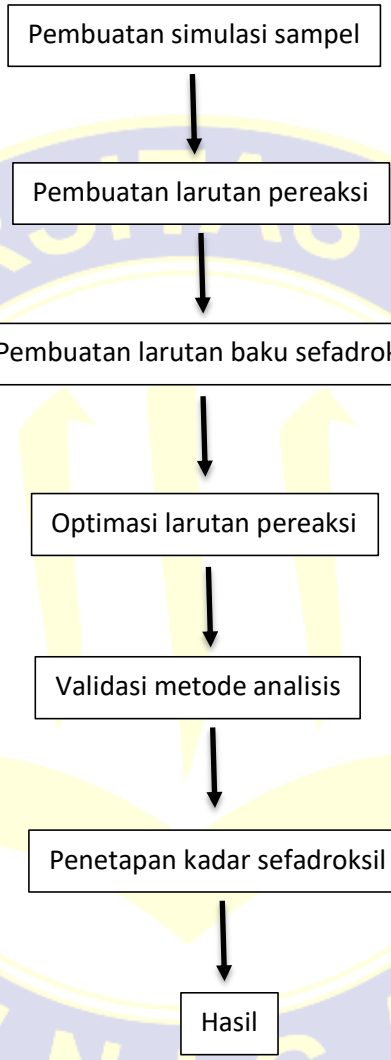
PREPARASI SAMPEL



Gambar V.4 Skema Preparasi Sampel

LAMPIRAN 7

ALUR PENELITIAN



Gambar V.5 Skema Alur Penelitian

LAMPIRAN 8

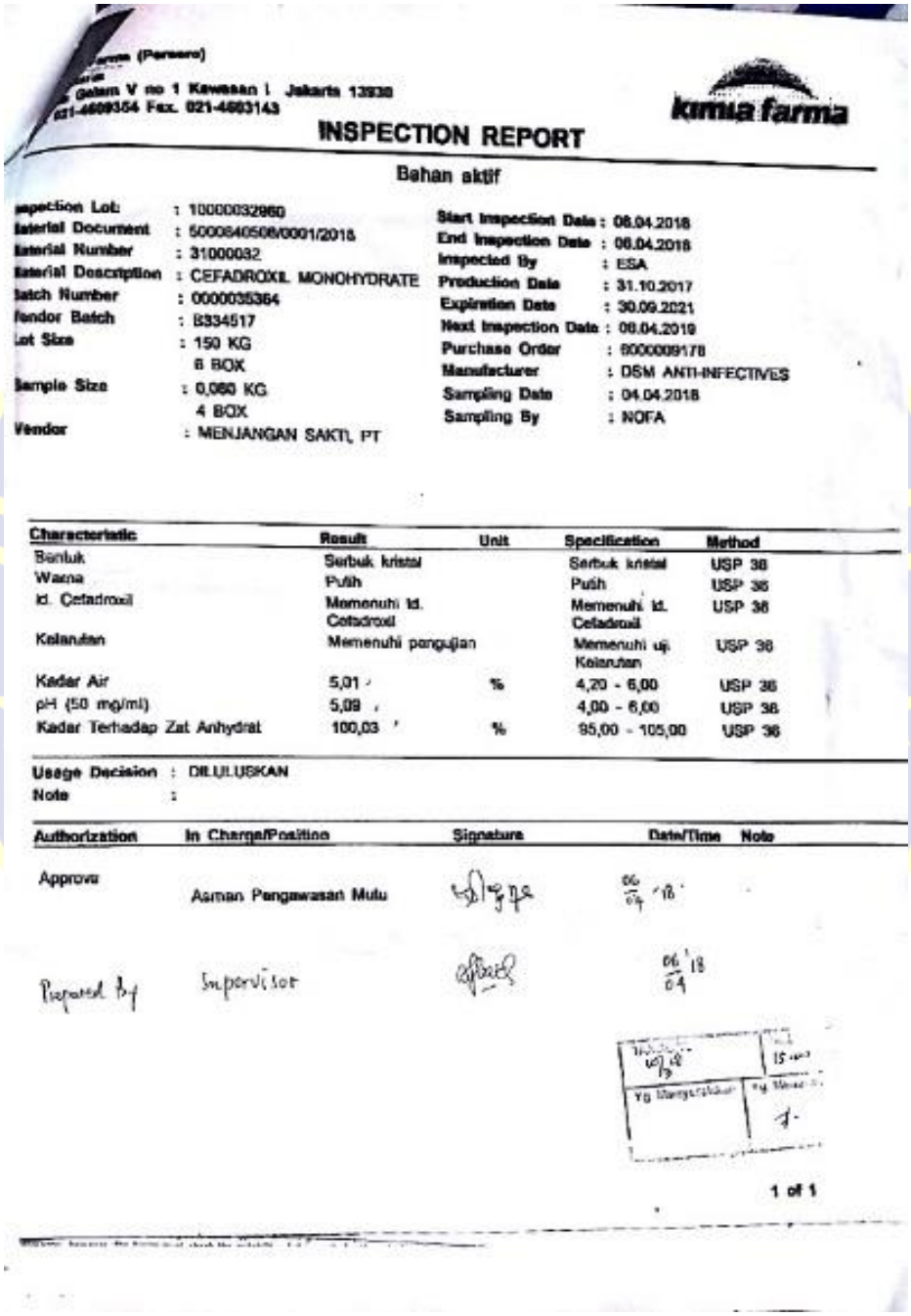
GAMBAR SAMPEL

Gambar V.6 Sampel suspensi merk “x”

Gambar V.7 Sampel suspensi simulasi

LAMPIRAN 9

CERTIFICATE OF ANALYSIS



(Persero)
Gatam V no 1 Kawasan I Jakarta 13930
021-4609354 Fax. 021-4603143

kimia farma

INSPECTION REPORT

Bahan aktif

Inspection Lot	: 10000032980	Start Inspection Date	: 06.04.2018
Material Document	: 5000840506/0001/2018	End Inspection Date	: 06.04.2018
Material Number	: 31000032	Inspected By	: ESA
Material Description	: CEFADROXIL MONOHYDRATE	Production Date	: 31.10.2017
Batch Number	: 0000035364	Expiration Date	: 30.09.2021
Vendor Batch	: 8334517	Next Inspection Date	: 06.04.2019
Lot Size	: 150 KG 6 BOX	Purchase Order	: 6000009178
		Manufacturer	: DSM ANTI-INFECTIVES
Sample Size	: 0,060 KG 4 BOX	Sampling Date	: 04.04.2018
		Sampling By	: NOFA
Vendor	: MENJANGAN SAKTI, PT		

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk kristal		Serbuk kristal	USP 38
Warna	Putih		Putih	USP 38
Id. Cefadroxil	Memenuhi Id. Cefadroxil		Memenuhi Id. Cefadroxil	USP 38
Kelarutan	Memenuhi pengujian		Memenuhi uji Kelarutan	USP 38
Kadar Air	5,01	%	4,20 - 6,00	USP 38
pH (50 mg/ml)	5,09		4,00 - 6,00	USP 38
Kadar Terhadap Zat Anhydrat	100,03	%	95,00 - 105,00	USP 38

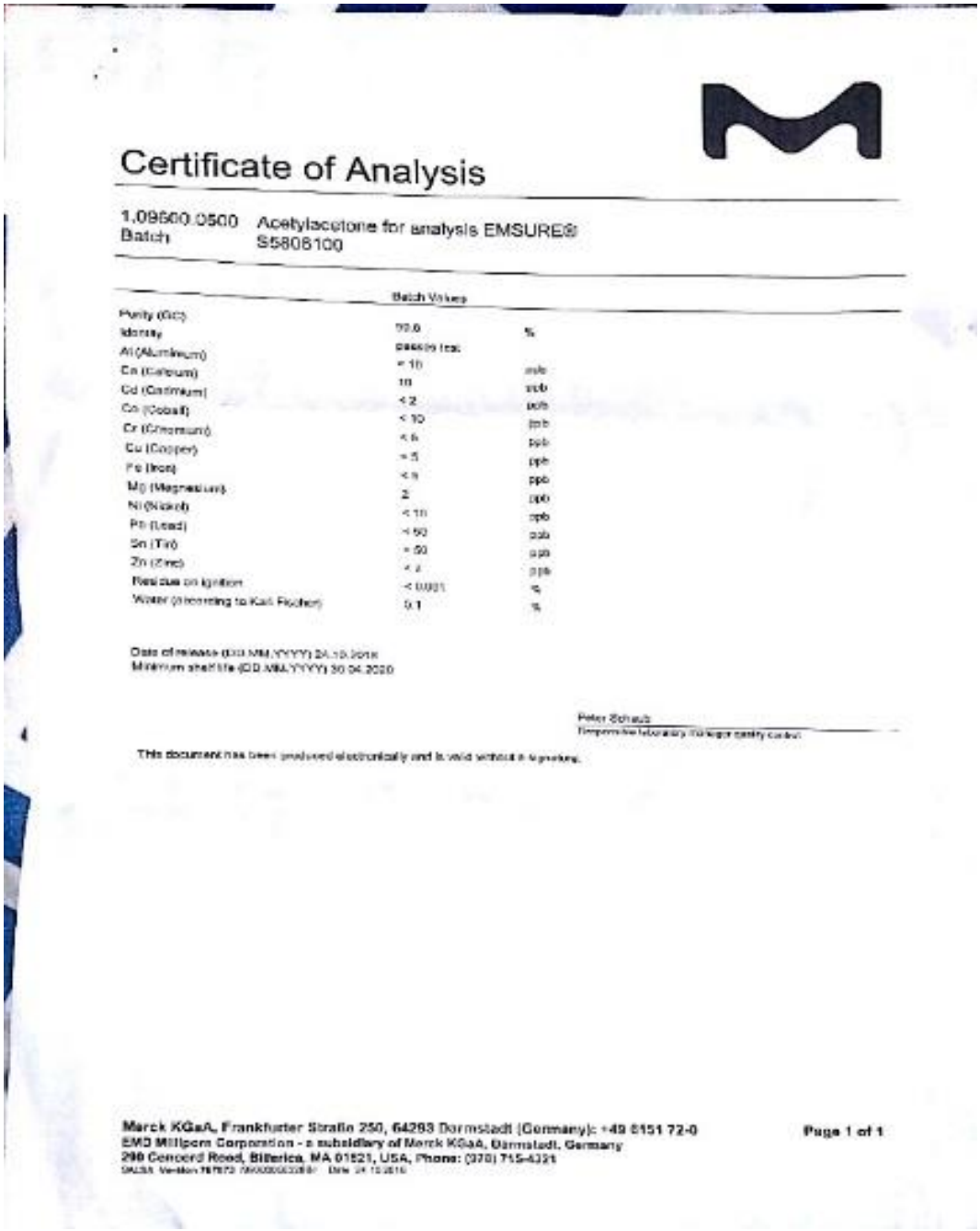
Usage Decision : DILULUSKAN
Note :

Authorization	In Charge/Position	Signature	Date/Time	Note
Approve	Asman Pengawasan Mutu		06/04/18	
Prepared By	Supervisor		06/04/18	

1 of 1

Gambar V. 8 Certificate of Analysis sefadroksil

LAMPIRAN 9
(LANJUTAN)



Certificate of Analysis

1.09500.0500 Acetylacetone for analysis EMSURE®
Batch S5806100

	Batch Values	
Purity (GC)	99.6	%
Identity	passes test	
Al (Aluminium)	< 10	ppb
Ca (Calcium)	10	ppb
Cd (Cadmium)	< 2	ppb
Co (Cobalt)	< 10	ppb
Cr (Chromium)	< 5	ppb
Cu (Copper)	< 5	ppb
Fe (Iron)	< 5	ppb
Mg (Magnesium)	2	ppb
Ni (Nickel)	< 10	ppb
Pb (Lead)	< 50	ppb
Sn (Tin)	< 50	ppb
Zn (Zinc)	< 2	ppb
Residue on ignition	< 0.001	%
Water (according to Karl Fischer)	0.1	%

Date of release (DD.MM.YYYY) 24.10.2018
Minimum shelf life (DD.MM.YYYY) 30.04.2020

Peter Schaub
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

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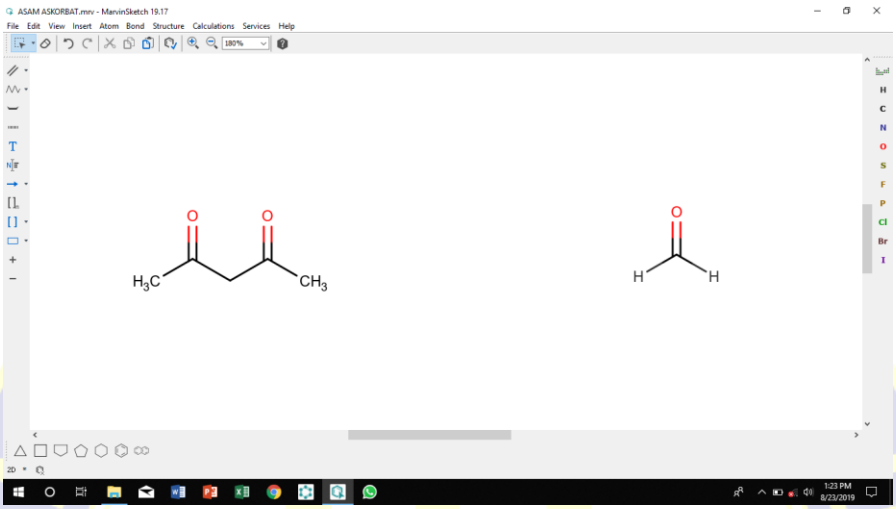
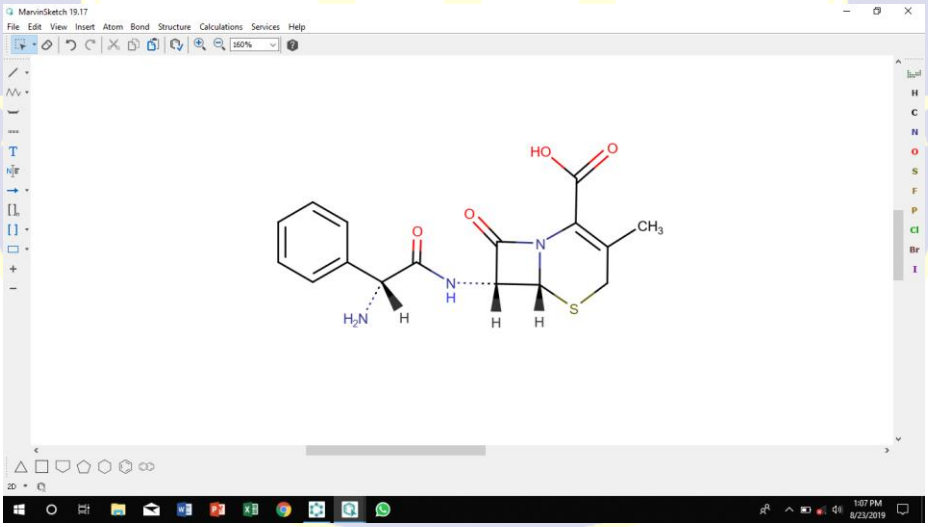
Gambar V.10 Certificate of Analysis Asetilaseton

LAMPIRAN 10

PEMBUATAN STRUKTUR



(a)



(b)

Gambar V.11 Pembuatan struktur dengan Marvinsketch