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LAMPIRAN 2

ANALISIS BAHAN BAKU OLEH PT. KIMIA FARMA

Plant Bandung
 Jl Pajajaran No 29 - 31 Bandung 40171
 Telp. 022- 4204043 Fax. 022-4237079

kimia farma

INSPECTION REPORT



Bahan aktif

Inspection Lot:	: 10000031483	Start Inspection Date :	: 19.03.2018
Material Document	: 5000831513/0001/2018	End Inspection Date :	: 19.03.2018
Material Number	: 31000127	Inspected By :	: RAMDHAN
Material Description	: ALBENDAZOLE	Production Date :	: 01.02.2018
Batch Number	: 0000034308	Expiration Date :	: 31.01.2023
Vendor Batch	: AEA000771A	Next Inspection Date :	: 20.03.2019
Lot Size	: 525 KG	Purchase Order :	: 6200000481
	: 21 DRM	Manufacturer :	: SEQUENT SCIENTIFIC LIMITED
Sample Size	: 0.017 KG	Sampling Date :	: 19.03.2018
	: 6 DRM	Sampling By :	: Zola
Vendor	: EPIC INGREDIENTS SDN BHD		

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk		Serbuk	USP 34
Warna	Putih sampai putih kekuningan		Putih sampai putih kekuningan	USP 34
Susut Pengerinan (%)	0.13	%	0.00 - 0.50	USP 34
Sisa Pemijaran (%)	0.02	%	0.00 - 0.20	USP 34
Kadar (%)	99.73	%	98.00 - 102.00	USP 34
Kelarutan dalam air	Praktis tidak larut dalam air		Praktis tidak larut dalam air	USP 34
Kelarutan dalam pelarut organik	Praktis tidak larut dalam alkohol		Praktis tidak larut dalam alkohol	USP 34
Identifikasi - Instrumen	Spektrum zat uji sesuai zat baku		Spektrum zat uji sesuai zat baku	USP 25
Jarak Lebur Awal	208.2	°C	min 208	The Merck Index
Jarak lebur akhir	209.6	°C	max 210	The Merck Index

Usage Decision : DILULUSKAN

Note :

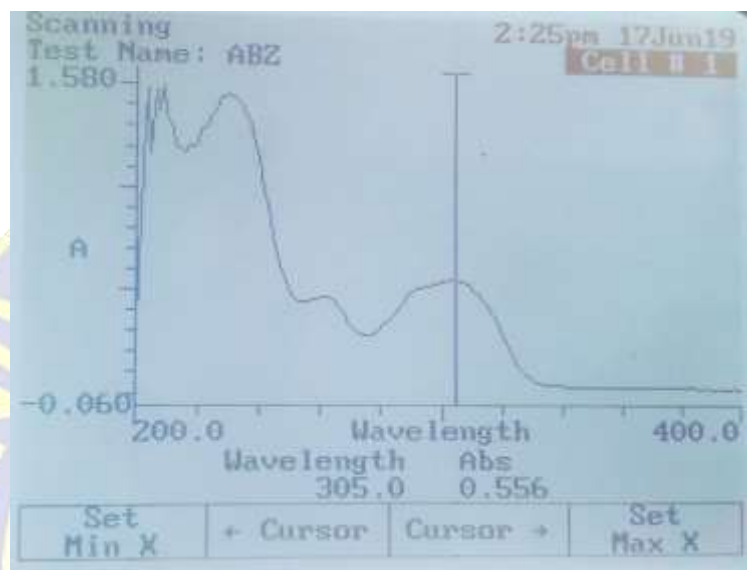
Authorization	In Charge/Position	Signature	Date/Time	Note
Prepared By	<u>Sofia Sunilawati, S.Si., Apt</u> Spv. Pem. Bahan Baku		20-03-2018	
Approve	<u>Nurul Fathonah, S.Farm., Apt</u> Asman Pengawasan Mutu		19-03-2018	

1 of 1

Gambar V.2 Laporan Analisa Bahan Baku Albendazol

LAMPIRAN 3

**PENETAPAN PANJANG GELOMBANG SERAPAN MAKSIMUM
ALBENDAZOL**



Gambar V.3 Serapan panjang Gelombang Maksimum Albendazol

Tabel V.1

Data Serapan Albendazol 10 $\mu\text{g/mL}$ Dalam Larutan Acidified methanol

Wavelength nm.	Abs.
305	0.556

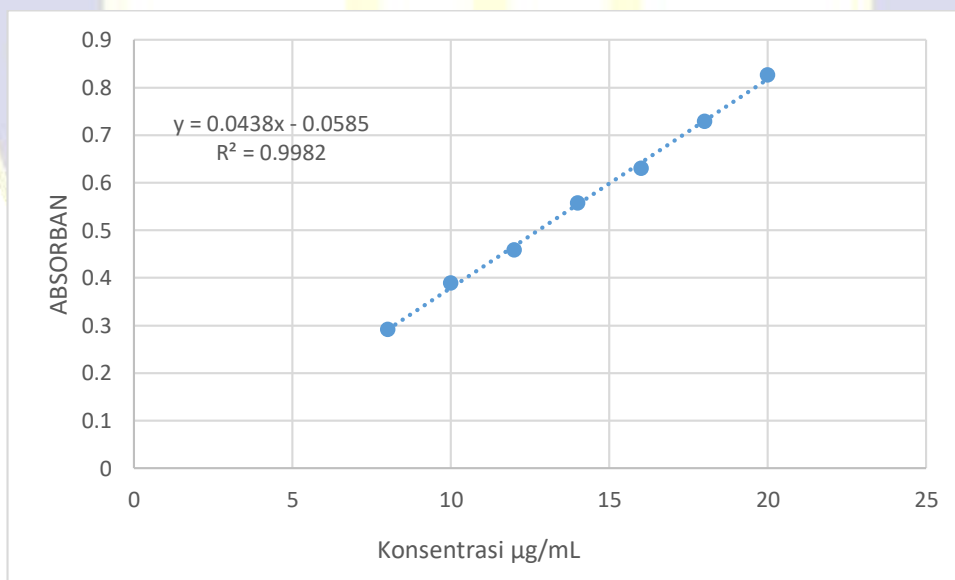
LAMPIRAN 4

PEMBUATAN KURVA STANDAR

Tabel V.2

Konsentrasi dan Serapan Kurva Kalibrasi Albendazol

Konsentrasi ($\mu\text{g/mL}$)	Serapan (Absorban)
8	0.292
10	0.389
12	0.459
14	0.558
16	0.630
18	0.729
20	0.826



Gambar V.4 Kurva Kalibrasi Albendazol

LAMPIRAN 5

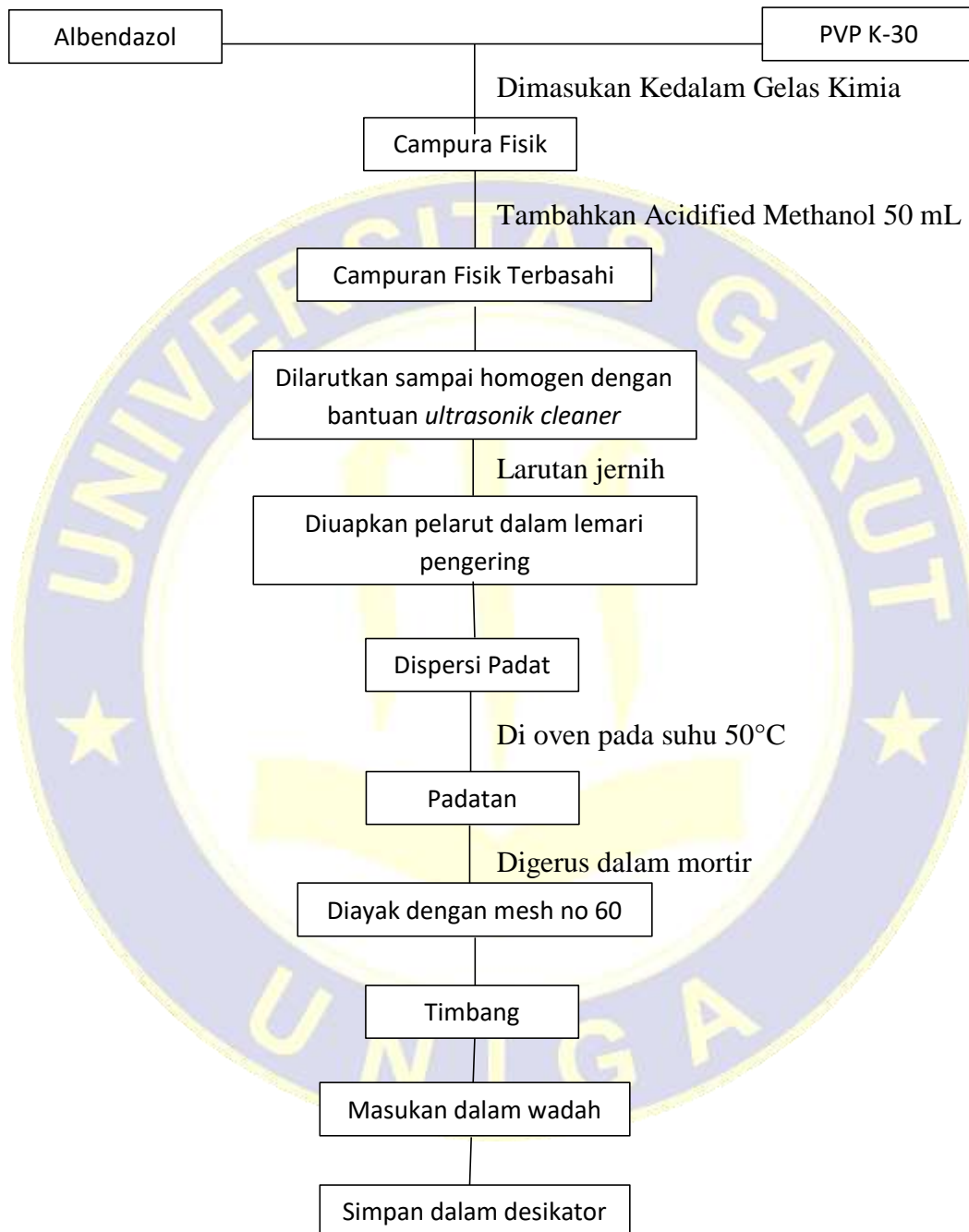
FORMULASI DISPERSI PADAT ALBENDAZOL DAN PVP-K30

Tabel V.3

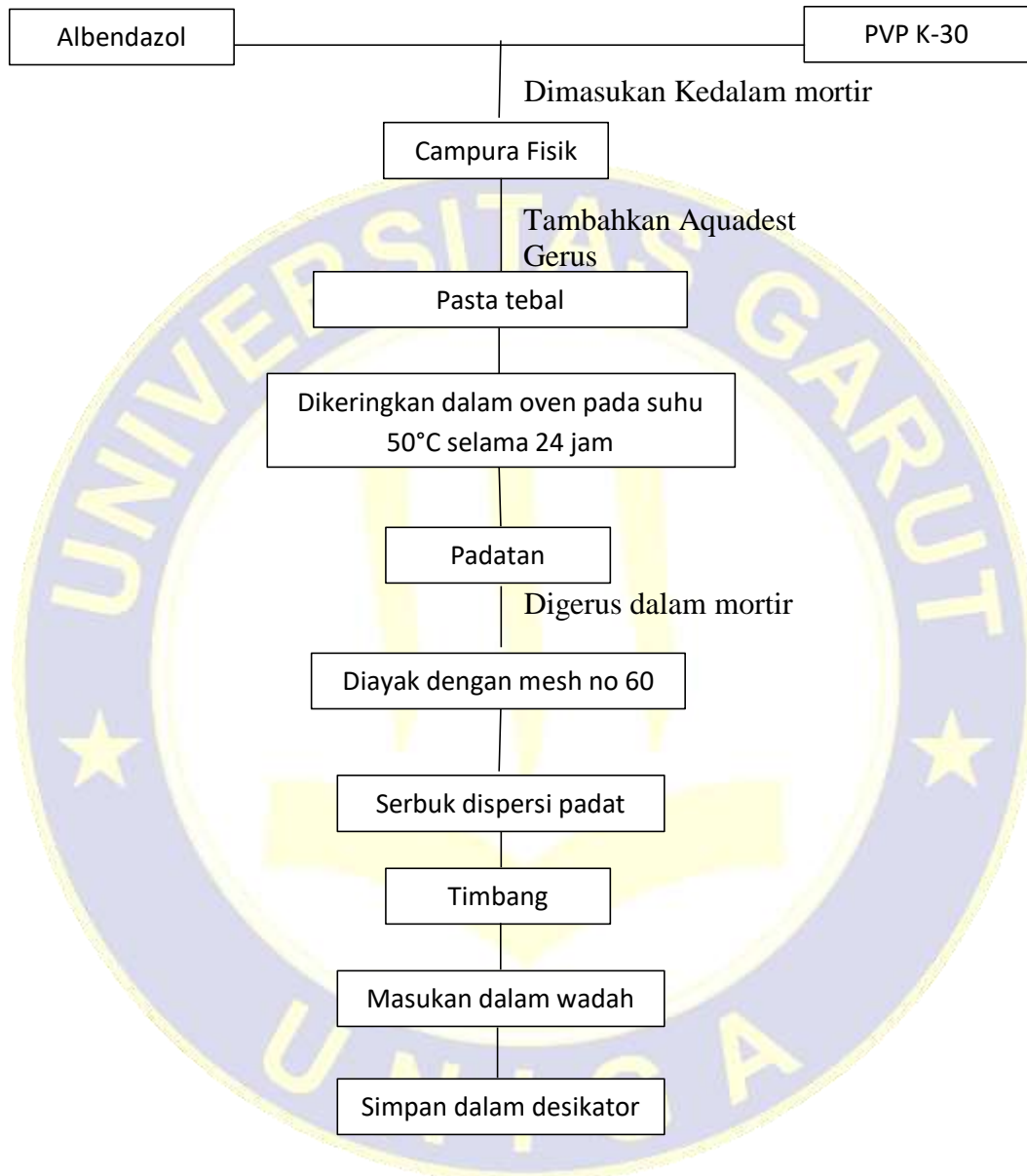
Formulasi Albendazol dan PVP K30

Metode	Perbandingan bobot		Albendazol (mg)	PVP K30 (mg)	Keterangan
	Albendazol	PVP K30			
SE 1	1	1	4000	4000	Solvent Evaporation
SE 2	1	2	4000	8000	
SE 3	1	3	4000	12000	
K 1	1	1	4000	4000	Kneading
K 2	1	2	4000	8000	
K 3	1	3	4000	12000	
CF 1	1	1	4000	4000	Campuran fisik
CF 2	1	2	4000	8000	
CF 3	1	3	4000	12000	

LAMPIRAN 6

PEMBUATAN METODE *SOLVENT EVAPORATION***Gambar V.5** Skema Pembuatan Dispersi Padat (*Solvent evaporation*)

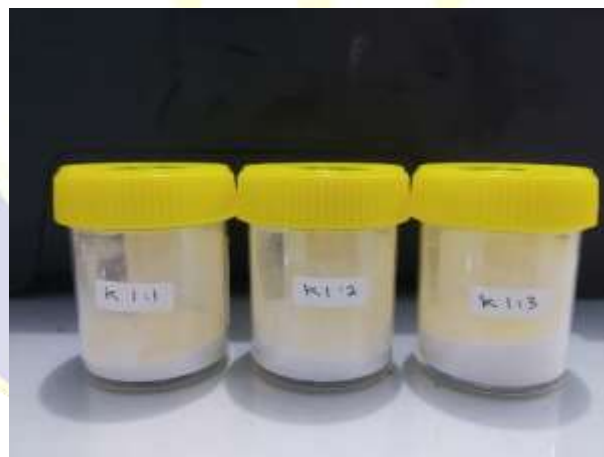
LAMPIRAN 7

PEMBUATAN METODE *KNEADING***Gambar V.6** Skema Pembuatan Dispersi Padat (*Kneading*)

LAMPIRAN 8**PEMBUATAN CAMPURAN FISIK****Gambar V.7** Skema Pembuatan Campuran Fisik

LAMPIRAN 9**SEDIAAN DISPERSI PADAT**

Gambar V.8 Dispersi Padat Metode *Solvent Evaporation*



Gambar V.9 Dispersi Padat Metode *Kneading*

LAMPIRAN 9
(LANJUTAN)



Gambar V.10 Campuran Fisik Albendazol- PVP K30



LAMPIRAN 10

**PERSENTASE HASIL CAMPURAN SOLVENT EVAPORATION,
KNEADING DAN CAMPURAN FISIK**

Tabel V.4

Bobot Akhir dan Persentase Hasil Campuran Metode *Solvent Evaporation*

Metode	Perbandingan Bobot	ABZ (mg)	PVP K30 (mg)	Bobot teori (mg)	Bobot Akhir (mg)	% Hasil Campuran
SE 1	1:1	4000	4000	8000	7303	91,29
SE 2	1:2	4000	8000	12000	11097	92,48
SE 3	1:3	4000	12000	16000	14512	90,70

Keterangan :

ABZ = Albendazol

SE 1 = *Solvent Evaporation* 1:1SE 2 = *Solvent Evaporation* 1:2SE 3 = *Solvent Evaporation* 1:3

Tabel V.5

Bobot Akhir dan Persentase Hasil Campuran Metode *Kneading*

Metode	Perbandingan Bobot	ABZ (mg)	PVP K30 (mg)	Bobot teori (mg)	Bobot Akhir (mg)	% Hasil Campuran
K 1	1:1	4000	4000	8000	7293	91.16
K 2	1:2	4000	8000	12000	11019	91.83
K 3	1:3	4000	12000	16000	14895	93.09

Keterangan :

ABZ = Albendazol

K 1 = *Kneading* 1:1K 2 = *Kneading* 1:2K 3 = *Kneading* 1:3

LAMPIRAN 10
(LANJUTAN)

Tabel V.6

` Bobot Akhir dan Persentase Hasil Campuran Campuran Fisik

Metode	Perbandingan Bobot	ABZ (mg)	PVP K30 (mg)	Bobot teori (mg)	Bobot Akhir (mg)	% Hasil Campuran
CF 1	1:1	4000	4000	8000	7898	98.73
CF 2	1:2	4000	8000	12000	11826	98.55
CF 3	1:3	4000	12000	16000	15932	99.58

Keterangan :

ABZ = Albendazol

CF 1 = Campuran Fisik 1:1

CF 2 = Campuran Fisik 1:2

CF 3 = Campuran Fisik 1:3

LAMPIRAN 11

PERSENTASE KANDUNGAN OBAT

Tabel V.7

Persentase Kandungan Obat

Metode	Absorban			% Kandungan Obat
	1	2	3	
SE 1	0,715	0,712	0,712	80,40
SE 2	0,479	0,482	0,481	85,38
SE 3	0,363	0,350	0,343	85,01
K 1	0.766	0.765	0.763	85.66
K2	0.496	0.498	0.496	87.29
K3	0.383	0.382	0.386	93.98
CF1	0.826	0.823	0.827	99.61
CF 2	0.490	0.497	0.496	93.29
CF 3	0.355	0.357	0.361	94.61

Keterangan :

CF 1 = Campuran Fisikl 1:1

CF 2 = Campuran Fisik 1:2

CF 3 = Campuran Fisik 1:3

K 1 = *Kneading* 1:1K 2 = *Kneading* 1:2K 3 = *Kneading* 1:3SE 1 = *Solvent Evaporation* 1:1SE 2 = *Solvent Evaporation* 1:2SE 3 = *Solvent Evaporation* 1:3

LAMPIRAN 12

UJI DISOLUSI DISPERSI PADAT

Tabel V.8

Persentase Terdisolusi

Menit Ke-	METODE									
	ABZ	CF 1	CF 2	CF 3	K 1	K 2	K 3	SE 1	SE 2	SE 3
0	0	0	0	0	0	0	0	0	0	0
5	2.41	23.48	32.71	32.95	62.79	61.97	49.16	66.83	54.37	57.69
10	3.54	52.88	60.55	66.17	73.18	79.3	77.82	76.92	73.33	72.54
20	5.14	54.23	68.5	70.46	76	81.63	80.89	79.76	78.27	79.03
30	10.24	61.81	72.24	74.05	77.06	83.15	81.56	81.46	84.79	85.91
45	14.09	63.6	72.94	75.83	82.07	83.21	80.07	81.57	86.10	87.31
50	16.26	63.9	73.63	75.95	84.27	83.84	82.45	82.38	87.27	88.40
60	20.7	68.25	74.63	76.06	85.2	85.83	86.62	86.89	87.37	88.62

Keterangan :

ABZ = Albendazol

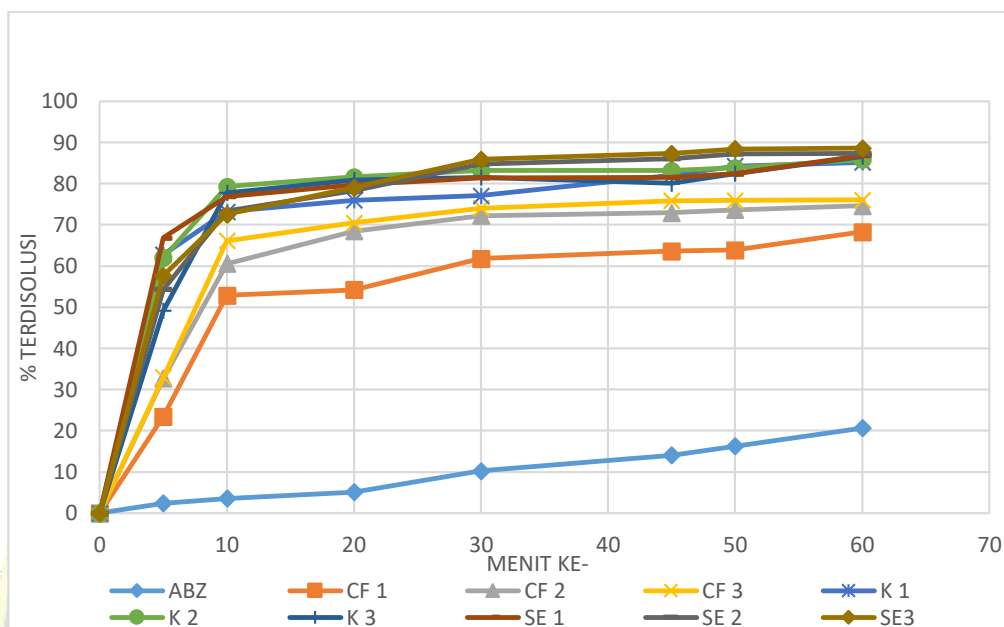
CF 1 = Campuran Fisikl 1:1

CF 2 = Campuran Fisik 1:2

CF 3 = Campuran Fisik 1:3

K 1 = *Kneading* 1:1K 2 = *Kneading* 1:2K 3 = *Kneading* 1:3SE 1 = *Solvent Evaporation* 1:1SE 2 = *Solvent Evaporation* 1:2SE 3 = *Solvent Evaporation* 1:3

LAMPIRAN 12
(LANJUTAN)



Gambar V.11 Grafik Persentase Terdisolusi Albendazol Murni dan Dispersi padat

Keterangan :

ABZ = Albendazol

CF 1 = Campuran Fisik 1:1

CF 2 = Campuran Fisik 1:2

CF 3 = Campuran Fisik 1:3

K 1 = *Kneading* 1:1

K 2 = *Kneading* 1:2

K 3 = *Kneading* 1:3

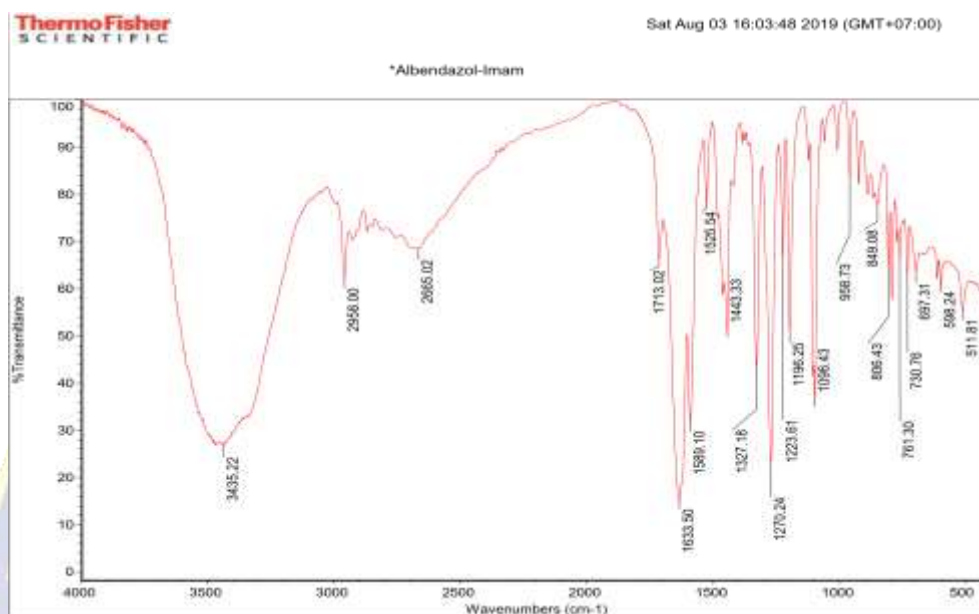
SE 1 = *Solvent Evaporation* 1:1

SE 2 = *Solvent Evaporation* 1:2

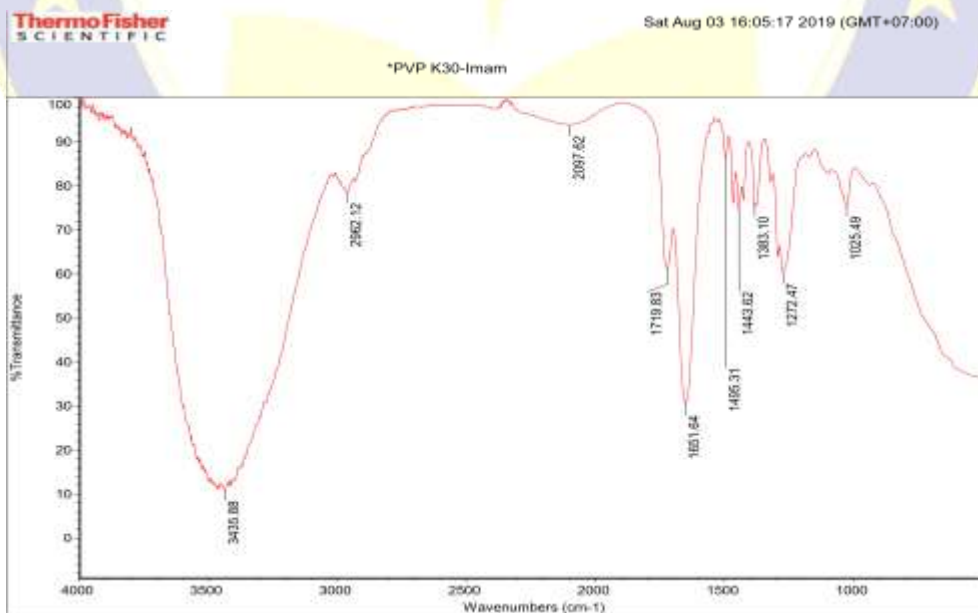
SE 3 = *Solvent Evaporation* 1:3

LAMPIRAN 13

KARAKTERISASI DISPERSI PADAT MENGGUNAKAN FTIR

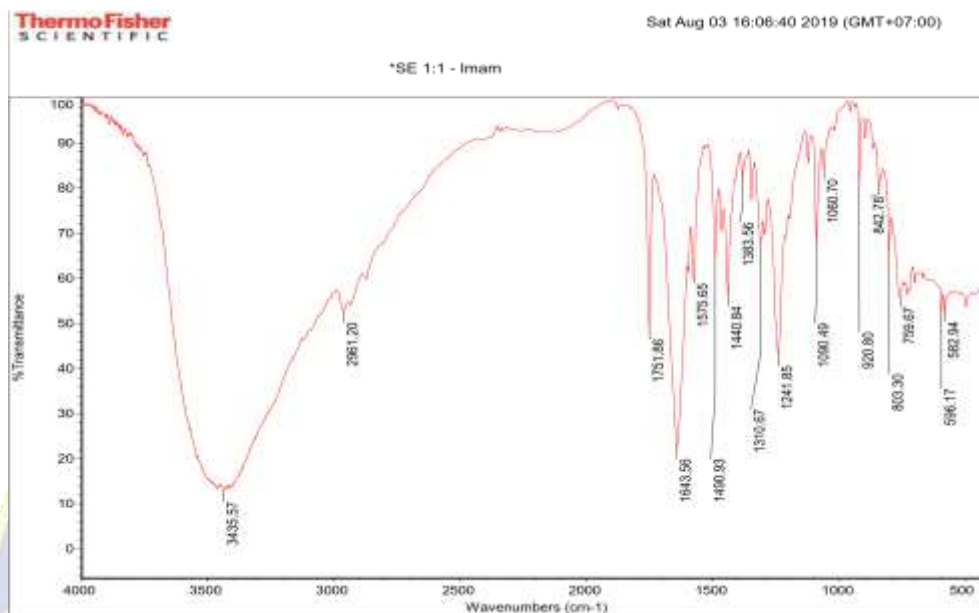


Gambar V.12 Spektrum Albendazol Murni

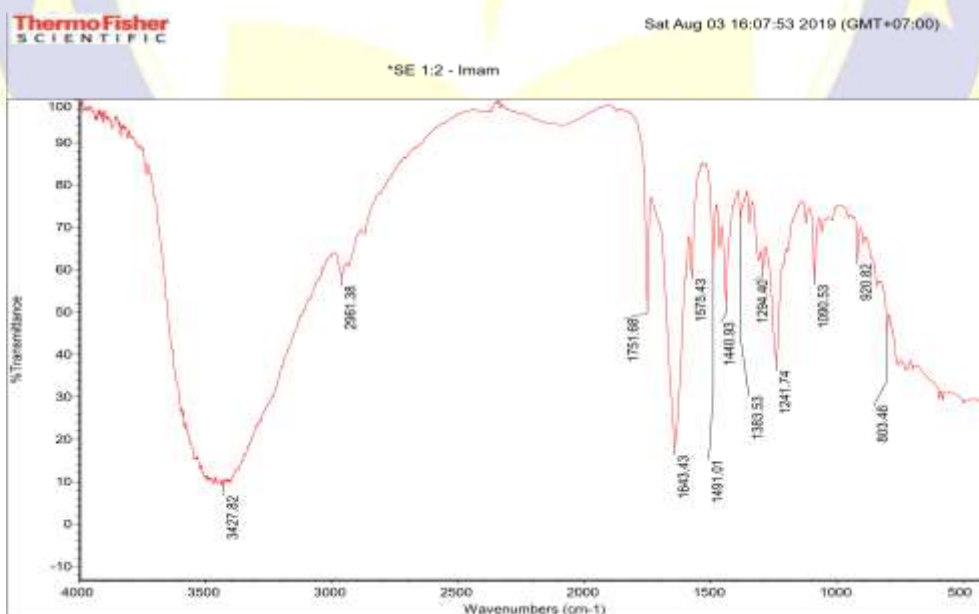


Gambar V.13 Spektrum PVP K-30

LAMPIRAN 13 (LANJUTAN)

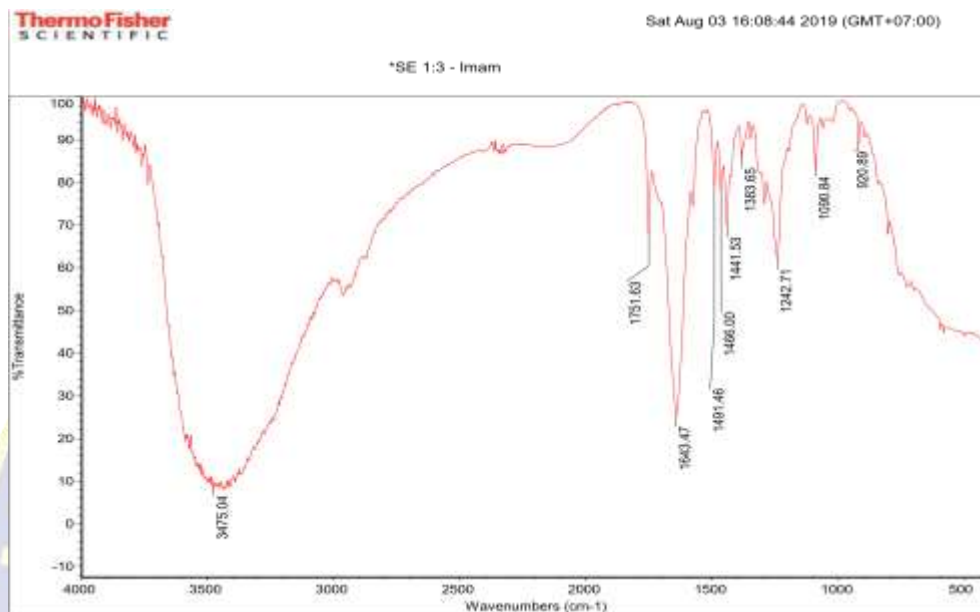


Gambar V.14 Spektrum Dispersi Padat *solvent evaporation* 1:1



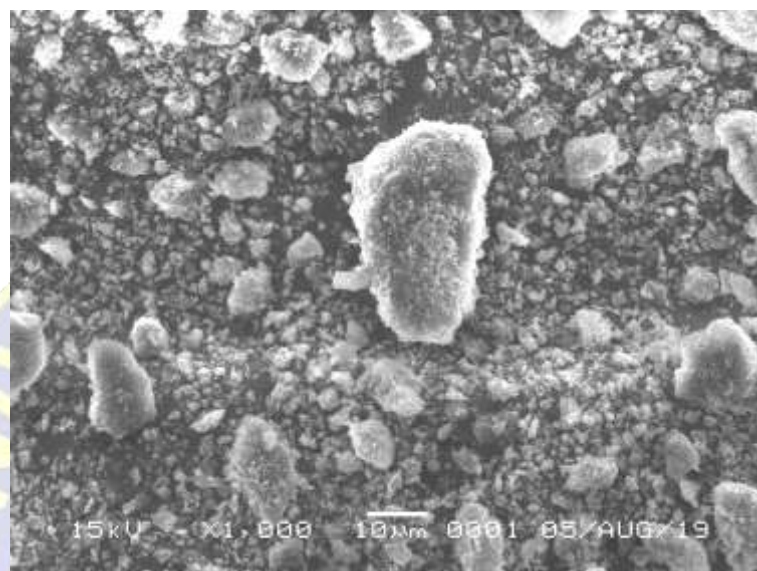
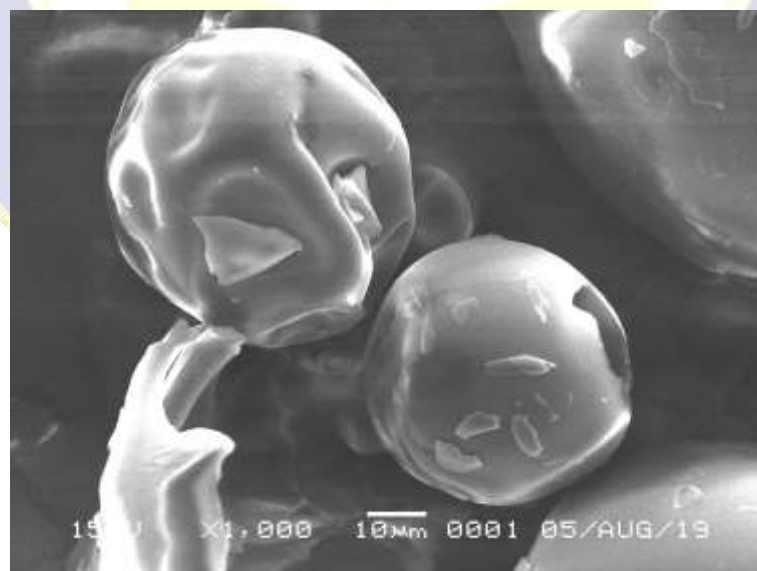
Gambar V.15 Spektrum Dispersi Padat *solvent evaporation* 1:2

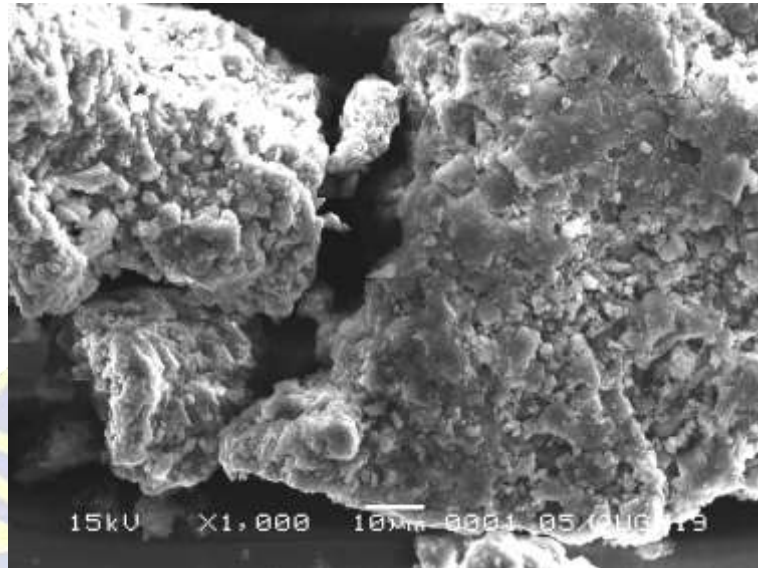
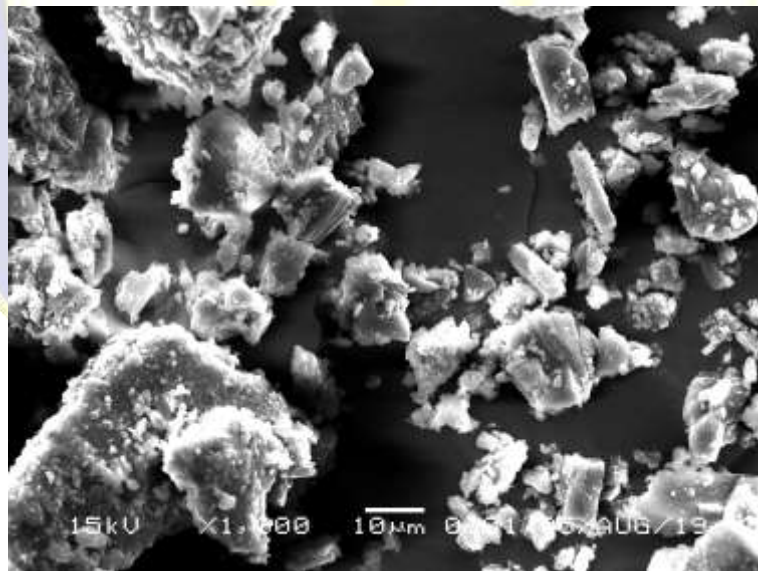
LAMPIRAN 13
(LANJUTAN)

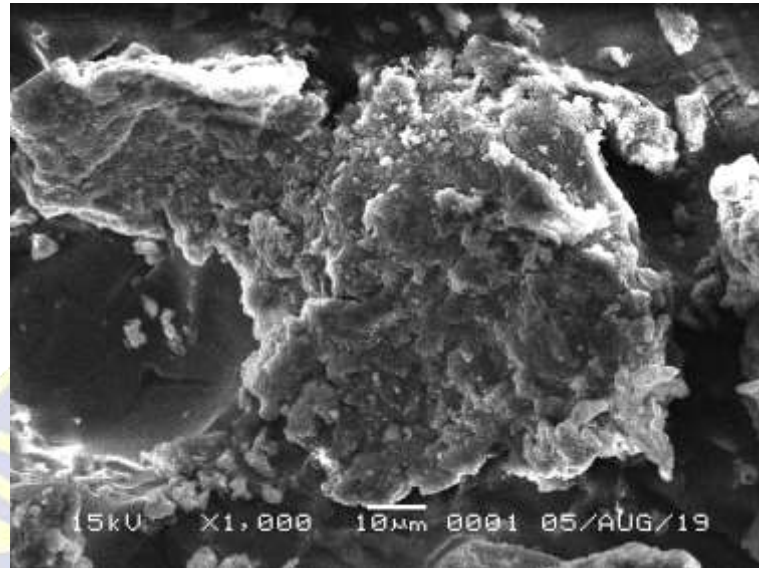


Gambar V.16 Spektrum Dispersi Padat *solvent evaporation* 1:3

UNIGA

LAMPIRAN 14**MORFOLOGI DISPERSI PADAT MENGGUNAKAN SCANNING
ELECTRON MICROSCOPY (SEM) PEMBESARAN 1000 X****Gambar V.17** Morfologi albendazol murni**Gambar V.18** Morfologi PVP K-30

LAMPIRAN 14**(LANJUTAN)****Gambar V.19** Morfologi Dispersi Padat *solvent evaporation* 1:1**Gambar V.20** Morfologi Dispersi Padat *solvent evaporation* 1:2

LAMPIRAN 14**(LANJUTAN)**

Gambar V.21 Morfologi Dispersi Padat *solvent evaporation* 1:3