

LAMPIRAN

Lampiran 1. Data Hasil Uji Keragaman Bobot

Formula	Bobot (mg)	Bobot rata-rata (mg)	Simpangan baku	Simpangan baku relatif (%)
I	202	221	18.01	8.15
	205			
	247			
	222			
	201			
	246			
	224			
	202			
	229			
	234			
II	250	243	14.41	5.9
	237			
	230			
	257			
	247			
	250			
	210			
	246			
	251			
	257			
III	222	232	16.02	6.9
	247			
	227			
	221			
	204			
	259			
	241			
	247			
	227			
	234			

Lampiran 2. Data Hasil Uji Penyerapan Lembab

Formula	Bobot Awal (mg)	Bobot Akhir (mg)	Penyerapan Lembab (%)	Rata-rata Penyerapan Lembab (%)	Simpangan baku
I	241	255	5.81	8.86	2.64
	270	298	10.37		
	221	244	10.41		
II	142	153	7.75	6.62	2.02
	256	267	4.29		
	268	289	7.83		
III	222	236	6.31	4.46	1,93
	241	247	2.45		
	217	227	4.61		

Contoh Perhitungan Penyerapan Lembab (%)

$$\text{Penyerapan lembab (\%)} = \frac{\text{Bobot akhir} - \text{Bobot awal}}{\text{Bobot awal}} \times 100$$

$$\text{Formula 1 replikasi 1} \rightarrow \text{Penyerapan lembab} = \frac{255-241}{241} \times 100 = 5,81\%$$



Lampiran 3. Data Hasil Uji Ketebalan Film

Formula	Tebal (cm)	Tebal Rata-rata (cm)	Simpangan baku
I	0.022	0.023	0.001
	0.024		
	0.022		
II	0.024	0.024	0
	0.024		
	0.024		
III	0.020	0.020	0
	0.020		
	0.020		



Lampiran 4. Data Hasil Uji Kandungan Zat Aktif

Formula I						
Abs	Kadar (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata Recovery (%)	Simpangan baku
0.407	8,85	40	354	88,5	87,77	0.81
0.404	8,79	40	351,6	87,9		
0.399	8,69	40	347,6	86,9		

Formula II						
Abs	Kadar (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata Recovery (%)	Simpangan baku
0.405	8,81	40	352,4	88,1	88,57	0.99
0.413	8,97	40	358,8	89,7		
0.404	8,79	40	351,6	87,9		

Formula III						
Abs	Kadar (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata Recovery (%)	Simpangan baku
0.399	8,69	40	347,6	86,9	87,10	1,32
0.406	8,83	40	353,2	88,3		
0.390	8,51	40	340,4	85,1		

Contoh Perhitungan Kandungan Zat Aktif Pravastatin Sodium

Persamaan Kurva Baku

$$Y = 0,0502X - 0,0372$$

Formula 1 Replikasi 1

$$0,407 = 0,0502 - 0,0372$$

$$X = \frac{0,407 + 0,0372}{0,0502}$$

$$X = 8,85 \text{ ppm}$$

Kadar Pravastatin Sodium = Kadar (ppm) x FP

$$= 8,85 \text{ ppm} \times 40$$

$$= 354 \text{ mg}$$

Recovery = $\frac{\text{Kadar Pravastatin Sodium (mg)}}{\text{Kadar Pravastatin Sodium Sesungguhnya}} \times 100 \%$

Kadar Pravastatin Sodium Sesungguhnya

$$= \frac{354 \text{ mg}}{400 \text{ mg}} \times 100\%$$

$$= 88,5\%$$

Lampiran 5. Data Hasil Uji Disolusi

Formula I Replikasi I								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.538	1	11.46	900	10.31	0	10.31	29.26
2	0.563	1	11.96	900	10.76	0.057	10.82	30.65
3	0.658	1	13.85	900	12.46	0.12	12.58	35.64
4	0.692	1	14.53	900	13.08	0.19	13.27	37.59
5	0.704	1	14.76	900	13.28	0.26	13.54	38.36
6	0.636	1	13.41	900	12.07	0.33	12.40	35.13

Formula I Replikasi II								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mcg)	Jumlah terlarut setelah dikoreksi (mcg)	% terlarut
1	0.185	2	8.85	900	7.96	0	7.96	21.40
2	0.201	2	9.49	900	8.54	0.04	8.58	23.06
3	0.265	2	12.04	900	10.84	0.09	10.93	29.38
4	0.300	2	13.43	900	12.09	0.15	12.24	32.90
5	0.323	2	14.35	900	12.92	0.22	13.14	35.32
6	0.629	2	26.54	900	23.89	0.29	24.18	65.00

Formula I Replikasi III								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mgg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.227	2	10.53	900	9.48	0	9.48	26.04
2	0.229	2	10.61	900	9.55	0.05	9.60	26.37
3	0.261	2	11.88	900	10.69	0.1	10.79	29.64
4	0.335	2	14.83	900	13.35	0.16	13.51	37.11
5	0.412	2	17.90	900	16.11	0.23	16.34	44.89
6	0.656	2	27.62	900	24.86	0.32	25.18	69.17

Formula II Replikasi I								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.420	1	9.11	900	8.20	0	8.20	23.77
2	0.458	1	9.86	900	8.87	0.046	8.92	25.85
3	0.506	1	10.82	900	9.74	0.095	9.83	28.49
4	0.528	1	11.26	900	10.13	0.149	10.28	29.80
5	0.585	1	12.39	900	11.15	0.205	11.36	32.93
6	0.609	1	12.87	900	11.58	0.267	11.85	34.35

Formula II Replikasi II								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.403	1	8.77	900	7.89	0	7.89	21.67
2	0.430	1	9.31	900	8.38	0.044	8.42	23.13
3	0.492	1	10.54	900	9.49	0.091	9.58	26.32
4	0.530	1	11.30	900	10.17	0.144	10.31	28.32
5	0.605	1	12.79	900	11.51	0.200	11.71	32.17
6	0.632	1	13.33	900	12.00	0.264	12.26	33.68

Formula II Replikasi III								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.225	1	5.22	900	4.7	0	4.7	13.31
2	0.350	1	7.71	900	6.94	0.026	6.97	19.41
3	0.419	1	9.09	900	8.18	0.065	8.25	22.98
4	0.442	1	9.55	900	8.60	0.110	8.71	24.26
5	0.510	1	10.90	900	9.81	0.158	9.97	27.78
6	0.581	1	12.31	900	11.08	0.212	11.29	31.45

Formula III Replikasi I								
Waktu (Jam)	Abs	F P	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.218	1	5.08	900	4.57	0	4.57	12.66
2	0.248	1	5.68	900	5.11	0.025	5.13	14.21
3	0.264	1	6	900	5.4	0.053	5.45	15.10
4	0.327	1	7.25	900	6.53	0.083	6.61	18.32
5	0.345	1	7.61	900	6.84	0.119	6.96	19.28
6	0.402	1	8.75	900	7.87	0.157	8.03	22.24

Formula III Replikasi II								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.225	1	5.22	900	4.7	0	4.7	13.39
2	0.253	1	5.78	900	5.2	0.026	5.23	14.90
3	0.321	1	7.14	900	6.43	0.055	6.49	18.41
4	0.462	1	9.94	900	8.95	0.091	9.04	25.75
5	0.494	1	10.58	900	9.52	0.141	9.66	27.52
6	0.500	1	10.70	900	9.63	0.194	9.82	27.98

Formula III Replikasi III								
Waktu (Jam)	Abs	FP	Kadar (mcg/ml)	Volume Medium (ml)	Jumlah terlarut (mg)	Koreksi (mg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0.250	1	5.72	900	5.15	0	5.15	15.10
2	0.335	1	7.41	900	6.67	0.029	6.70	19.65
3	0.387	1	8.45	900	7.61	0.074	7.68	22.52
4	0.522	1	11.14	900	10.03	0.116	10.15	29.76
5	0.587	1	12.43	900	11.19	0.172	11.36	33.31
6	0.628	1	13.25	900	11.93	0.234	12.16	35.65

Jam	Nilai persen terlarut(%) $\pm$ Simpangan baku		
	F I	F II	F III
1	25.57 $\pm$ 3.9	19.58 $\pm$ 5.5	13.72 $\pm$ 1.2
2	26.69 $\pm$ 3.8	16.25 $\pm$ 2.9	16.25 $\pm$ 2.9
3	31.55 $\pm$ 3.5	25.93 $\pm$ 2.7	18.68 $\pm$ 3.7
4	35.87 $\pm$ 2.6	27.46 $\pm$ 2.8	24.61 $\pm$ 5.8
5	39.52 $\pm$ 4.9	30.96 $\pm$ 2.8	26.70 $\pm$ 7.0
6	56.43 $\pm$ 18.6	33.16 $\pm$ 1.5	28.62 $\pm$ 6.7

1. Perhitungan bobot aktual formula 1 replikasi 1
 - a. (% rata-rata kandungan zat aktif x berat obat yang ditimbang)

$$= 87,77\% \times 40 \text{ mg}$$

$$= 35,1 \text{ mg}$$
 - b.
$$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{222 \times 35,1 \text{ mg}}{221}$$

$$= 35,3 \text{ mg}$$
2. Perhitungan bobot aktual formula 1 replikasi 2
 - a. (% rata-rata kandungan zat aktif x berat obat yang ditimbang)

$$= 87,77\% \times 40 \text{ mg}$$

$$= 35,1 \text{ mg}$$
 - b.
$$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{234 \times 35,1 \text{ mg}}{221}$$

$$= 37,2 \text{ mg}$$
3. Perhitungan bobot aktual formula 1 replikasi 3
 - a. (% rata-rata kandungan zat aktif x berat obat yang ditimbang)

$$= 87,77\% \times 40 \text{ mg}$$

$$= 35,1 \text{ mg}$$
 - b.
$$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{229 \times 35,1 \text{ mg}}{221}$$

$$= 36,4 \text{ mg}$$
4. Perhitungan bobot aktual formula 2 replikasi 1
 - a. (% rata-rata kandungan zat aktif x berat obat yang ditimbang)

$$= 88,57\% \times 40 \text{ mg}$$

$$= 35,4 \text{ mg}$$
 - b.
$$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{237 \times 35,4 \text{ mg}}{243}$$

$$= 34,5 \text{ mg}$$
5. Perhitungan bobot aktual formula 2 replikasi 2
 - a. (% rata-rata kandungan zat aktif x berat obat yang ditimbang)

$$= 88,73\% \times 40 \text{ mg}$$

$$= 35,4 \text{ mg}$$
 - b.
$$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{250 \times 35,4 \text{ mg}}{243}$$

$$= 36,4 \text{ mg}$$

6. Perhitungan bobot aktual formula 2 replikasi 3
- (% rata-rata kandungan zat aktif x berat obat yang ditimbang)
 $= 88,73\% \times 40 \text{ mg}$
 $= 35,49 \text{ mg}$
 - $$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{246 \times 35,49 \text{ mg}}{243}$$

$$= 35,9 \text{ mg}$$
7. Perhitungan bobot aktual formula 3 replikasi 1
- (% rata-rata kandungan zat aktif x berat obat yang ditimbang)
 $= 87,10\% \times 40 \text{ mg}$
 $= 34,8 \text{ mg}$
 - $$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{241 \times 34,8 \text{ mg}}{232}$$

$$= 36,1 \text{ mg}$$
8. Perhitungan bobot aktual formula 3 replikasi 2
- (% rata-rata kandungan zat aktif x berat obat yang ditimbang)
 $= 87,10\% \times 40 \text{ mg}$
 $= 34,8 \text{ mg}$
 - $$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{234 \times 34,8 \text{ mg}}{232}$$

$$= 35,1 \text{ mg}$$
9. Perhitungan bobot aktual formula 3 replikasi 1
- (% rata-rata kandungan zat aktif x berat obat yang ditimbang)
 $= 87,10\% \times 40 \text{ mg}$
 $= 34,8 \text{ mg}$
 - $$\frac{(\text{bobot film yang ditimbang} \times \% \text{ rata-rata kandungan zat aktif} \times \text{berat obat yang ditimbang})}{\text{bobot rata-rata film}}$$

$$= \frac{227 \times 34,8 \text{ mg}}{232}$$

$$= 34,1 \text{ mg}$$

Lampiran 6. Data Statistik Uji Ketebalan

Tests of Normality^{b,c}

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	Df	Sig.
Ketebalan f1 7:3	.385	3	.	.750	3	.000

a. Lilliefors Significance Correction

b. ketebalan is constant when formula = f2 6:4. It has been omitted.

c. ketebalan is constant when formula = f3 5:5. It has been omitted.

Test of Homogeneity of Variances

Ketebalan

Levene Statistic	df1	df2	Sig.
16.000	2	6	.004

Ranks

formula	N	Mean Rank
Ketebalan f1 7:3	3	5.50
f2 6:4	3	7.50
f3 5:5	3	2.00
Total	9	

Test Statistics^{a,b}

	Ketebalan
Chi-Square	7.086
Df	2
Asymp. Sig.	.029

a. Kruskal Wallis Test

b. Grouping Variable:

formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
Ketebalan	f1 7:3	3	5.00	15.00
	f3 5:5	3	2.00	6.00
	Total	6		

Test Statistics^b

	Ketebalan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-2.121
Asymp. Sig. (2-tailed)	.034
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
Ketebalan	f1 7:3	3	2.50	7.50
	f2 6:4	3	4.50	13.50
	Total	6		

Test Statistics^b

	Ketebalan
Mann-Whitney U	1.500
Wilcoxon W	7.500
Z	-1.581
Asymp. Sig. (2-tailed)	.114
Exact Sig. [2*(1-tailed Sig.)]	.200 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
Ketebalan	f2 6:4	3	5.00	15.00
	f3 5:5	3	2.00	6.00
	Total	6		

Test Statistics^b

	Ketebalan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-2.236
Asymp. Sig. (2-tailed)	.025
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Lampiran 7. Data Statistik Uji Penyerapan lembab

Tests of Normality							
Formula		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
penyerapanlembab	f1 7:3	.382	3	.	.757	3	.014
	f2 6:4	.378	3	.	.767	3	.038
	f3 5:5	.198	3	.	.995	3	.869

a. Lilliefors Significance Correction

Test of Homogeneity of Variances

Penyerapanlembab

Levene Statistic	df1	df2	Sig.
.501	2	6	.629

Ranks

Formula		N	Mean Rank
penyerapanlembab	f1 7:3	3	7.00
	f2 6:4	3	5.00
	f3 5:5	3	3.00
Total		9	

Test Statistics^{a,b}

	Penyerapanlembab
	ab
Chi-Square	3.200
Df	2
Asymp. Sig.	.202

a. Kruskal Wallis Test

b. Grouping Variable: Formula

Lampiran 8. Data Statistik Uji Keragaman Bobot

Tests of Normality

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Keragamanbobot f1 7:3	.216	10	.200*	.882	10	.136
f2 6:4	.269	10	.039	.832	10	.036
f3 5:5	.144	10	.200*	.975	10	.933

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Test of Homogeneity of Variances

Keragamanbobot

Levene Statistic	df1	df2	Sig.
.582	2	27	.566

Ranks

formula	N	Mean Rank
Keragamanbobot f1 7:3	10	10.00
f2 6:4	10	21.40
f3 5:5	10	15.10
Total	30	

Test Statistics^{a,b}

	Keragamanbobo t
Chi-Square	8.447
Df	2
Asymp. Sig.	.015

a. Kruskal Wallis Test

b. Grouping Variable: formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
keragamanbobot	f1 7:3	10	6.80	68.00
	f2 6:4	10	14.20	142.00
	Total	20		

Test Statistics^b

	Keragamanbobot
Mann-Whitney U	13.000
Wilcoxon W	68.000
Z	-2.802
Asymp. Sig. (2-tailed)	.005
Exact Sig. [2*(1-tailed Sig.)]	.004 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
keseragamanbobot	f1 7:3	10	8.70	87.00
	f3 5:5	10	12.30	123.00
	Total	20		

Test Statistics^b

	Keragamanbobo t
Mann-Whitney U	32.000
Wilcoxon W	87.000
Z	-1.365
Asymp. Sig. (2-tailed)	.172
Exact Sig. [2*(1-tailed Sig.)]	.190 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Ranks

	formula	N	Mean Rank	Sum of Ranks
keragamanbobot	f2 6:4	10	12.70	127.00
	f3 5:5	10	8.30	83.00
	Total	20		

Test Statistics^b

	keragamanbobot
Mann-Whitney U	28.000
Wilcoxon W	83.000
Z	-1.667
Asymp. Sig. (2-tailed)	.095
Exact Sig. [2*(1-tailed Sig.)]	.105 ^a

a. Not corrected for ties.

b. Grouping Variable: formula

Lampiran 9. Data Statistik Uji Kandungan Zat Aktif

Tests of Normality

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
kandungan f17:3	.232	3	.	.980	3	.726
f26:4	.349	3	.	.832	3	.194
f35:5	.200	3	.	.995	3	.862

a. Lilliefors Significance Correction

Test of Homogeneity of Variances

kandungan

Levene Statistic	df1	df2	Sig.
.670	2	6	.546

ANOVA

kandungan	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4.880	2	2.440	1.743	.253
Within Groups	8.400	6	1.400		
Total	13.280	8			

Multiple Comparisons

kandungan

Tukey HSD

(I) formula	(J) formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
f17:3	f26:4	-.8000	.9661	.701	-3.764	2.164
	f35:5	1.0000	.9661	.584	-1.964	3.964
f26:4	f17:3	.8000	.9661	.701	-2.164	3.764
	f35:5	1.8000	.9661	.229	-1.164	4.764
f35:5	f17:3	-1.0000	.9661	.584	-3.964	1.964
	f26:4	-1.8000	.9661	.229	-4.764	1.164

*. The mean difference is significant at the 0.05 level.



Lampiran 10. Data Statistik Uji Disolusi

Tests of Normality

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
ujidisolusi f17:3	.210	6	.200 [*]	.880	6	.269
f26:4	.189	6	.200 [*]	.946	6	.712
f35:5	.200	6	.200 [*]	.927	6	.554

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Test of Homogeneity of Variances

ujidisolusi

Levene Statistic	df1	df2	Sig.
.736	2	15	.496

ANOVA

ujidisolusi					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	670.600	2	335.300	4.829	.024
Within Groups	1041.557	15	69.437		
Total	1712.157	17			

Multiple Comparisons

ujidisolusi

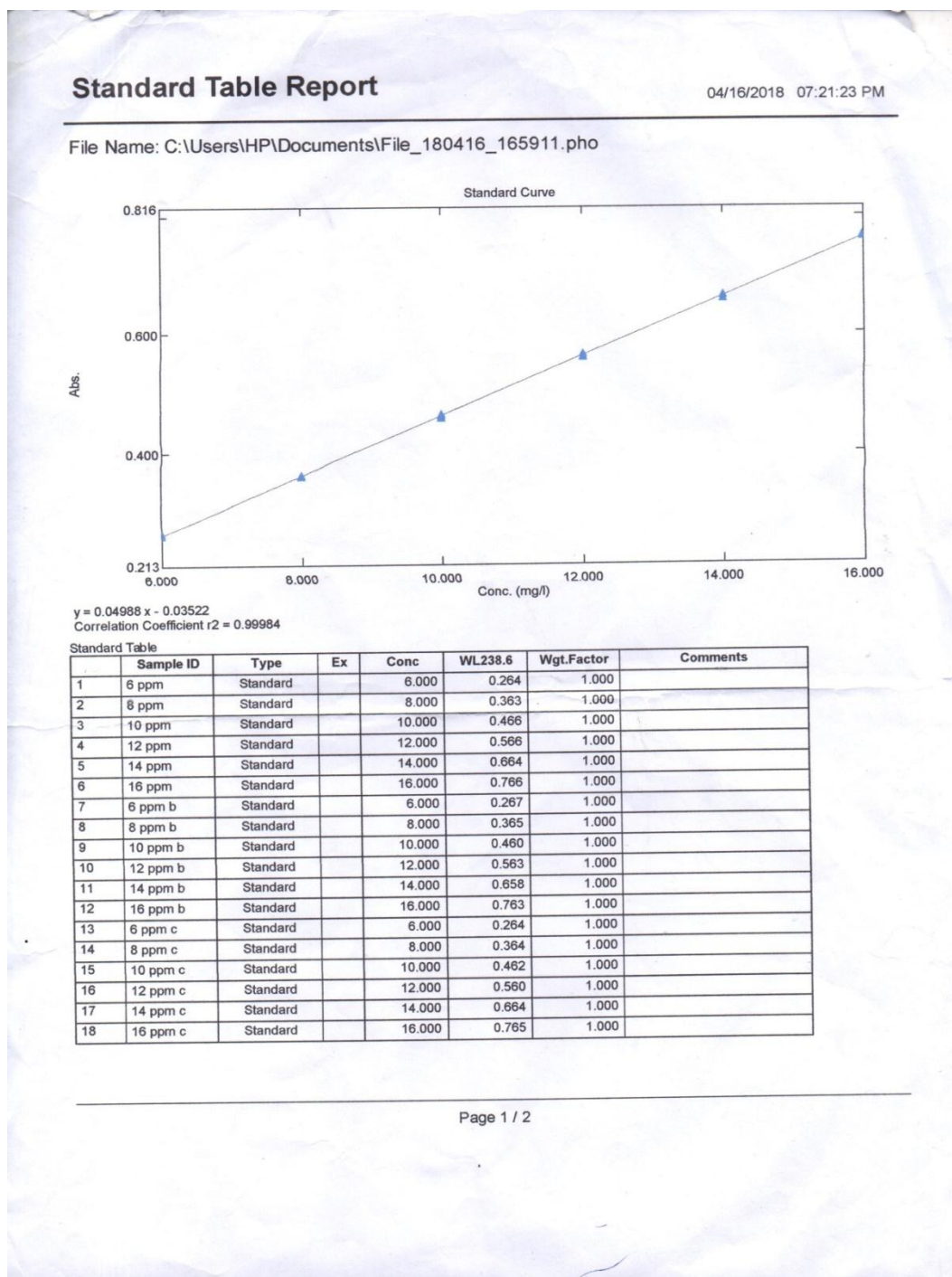
Tukey HSD

(I) formula	(J) formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
f17:3	f26:4	10.38167	4.81100	.112	-2.1148	22.8781
	f35:5	14.50833*	4.81100	.022	2.0119	27.0048
f26:4	f17:3	-10.38167	4.81100	.112	-22.8781	2.1148
	f35:5	4.12667	4.81100	.674	-8.3698	16.6231
f35:5	f17:3	-14.50833*	4.81100	.022	-27.0048	-2.0119
	f26:4	-4.12667	4.81100	.674	-16.6231	8.3698

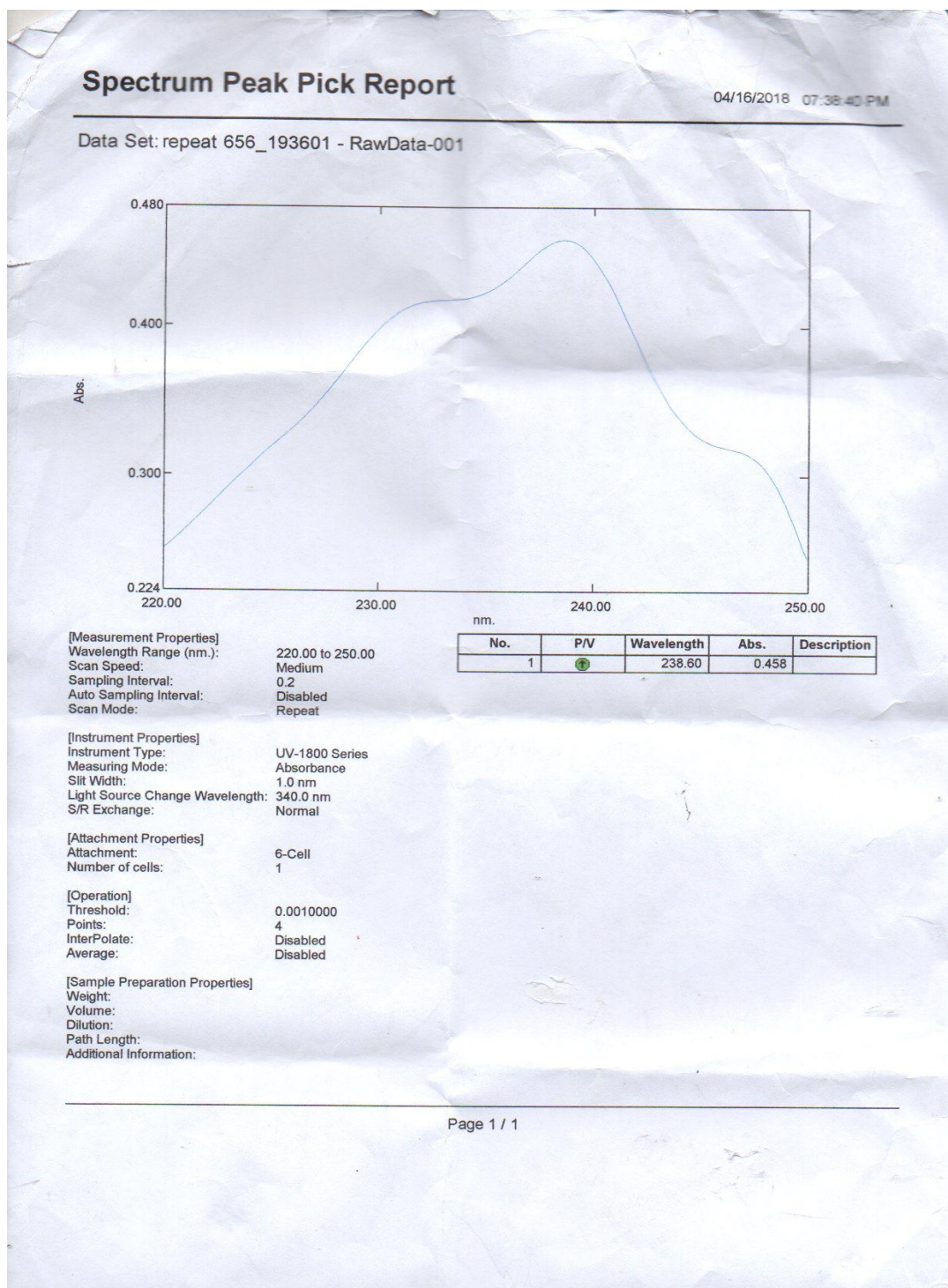
*. The mean difference is significant at the 0.05 level.



Lampiran 11. Data Absorbansi Kurva Baku



Lampiran 12. Panjang gelombang Maksimal



Lampiran 13. *Certificat of Analysis* Pravastatin Sodium


Biocon Limited
Biocon Special Economic Zone
Plot Nos. 2 - 4, Phase IV
Bommasandra-Itanagi Link Road
Bommasandra Post
Bangalore 560 099, India
T 91 80 7808 2808
F 91 80 2852 3423
www.biocon.com

CERTIFICATE OF ANALYSIS
QUALITY ASSURANCE

Product Name: PRAVASTATIN SODIUM Ph.Eur.	A.R.No. : 40000150934	Page No. : 1 of 2
Batch No. /Disp. Ref. No. : BS17001406/BF17003921	Manufacturing date: July 2017	
Quantity : 3.00 kg	Expiry date : June 2020	

Ph. Eur. and In-house Specifications:

TESTS	OBSERVATIONS	LIMITS
Characters:		
a. Appearance	White crystalline powder, hygroscopic	a. White or yellowish white powder or crystalline powder, hygroscopic.
b. Solubility	Complies	b. Freely soluble in Water and in Methanol. Soluble in anhydrous ethanol.
Identification		
a. By SOR	Complies	a. It complies with test for specific optical rotation.
b. By IR Absorption	Complies	b. IR spectrum of sample matches with the Ph.Eur. Reference spectrum of Pravastatin sodium.
c. By test for Sodium	Complies	c. It complies for the test for sodium.
Appearance of solution	Complies	The solution should be clear and not more intensely colored than reference solution BY ₆
pH	7.46	Between 7.20 and 9.00
*Specific optical rotation $[\alpha]_D^{20^\circ}$, in water	+157°	Between +153° and +159°
Related substances (by HPLC)	Below disregard limit Not detected 0.076% Below disregard limit Below detection level Below detection level Below disregard limit 0.076%	Impurity A (6'-epipravastatin) - NMT 0.30% Impurity B (3''-(R)-hydroxypravastatin) - NMT 0.20% Impurity C - NMT 0.20% Impurity D (Pravastatin lactone) - NMT 0.20% Impurity E (Diastereomer of hydroxypravastatin sodium) [3''-(S)-hydroxypravastatin] - NMT 0.20% Impurity G - NMT 0.15% Maximum individual unspecified impurity - NMT 0.10% Total impurities - NMT 0.60%
Methanol content (By GC)	0.01%	Not more than 3.00%w/w
Heavy metals	Less than 20 ppm	Not more than 0.002% (20 ppm)
Water content (by KF)	1.95%	Not more than 4.00%w/w

Prepared by : *[Signature]*
 Date : 25/09/2017

Checked by : *[Signature]*
 Date : 25/09/2017

Approved by : *[Signature]*
 Date : 25/09/2017
 (Quality Assurance)

Lampiran 14. Surat Keterangan Telah Selasai Melakukan Penelitian

 UNIVERSITAS WAHID HASYIM
FAKULTAS FARMASI
BAGIAN FARMASETIKA
Jl. Menoreh Tengah X / 22 Sampangan – Semarang 50236 Telp. (024) 8505680 – 8505681 fax. (024) 8505680

SURAT KETERANGAN
No. 011/Lab. Farmasetika/C.05/UWH/V/2018

Assalamu'alaikum Wr. Wb.

Yang bertanda tangan dibawah ini, Kepala Bagian Farmasi Fisika & Farmasetika Fakultas Farmasi Universitas Wahid Hasyim Semarang menerangkan bahwa :

Nama : Aisyah
NIM : 145010171
Fakultas : Farmasi

Telah melakukan formulasi di Laboratorium Teknologi Farmasi dalam rangka penelitian dengan judul :

“Formulasi Film Transdermal Pravastatin Sodium Dengan Kombinasi Polimer Polivinil Alkohol (PVA) dan Etil Selulosa (EC)”.

Demikian surat keterangan ini dibuat untuk dipergunakan semestinya.

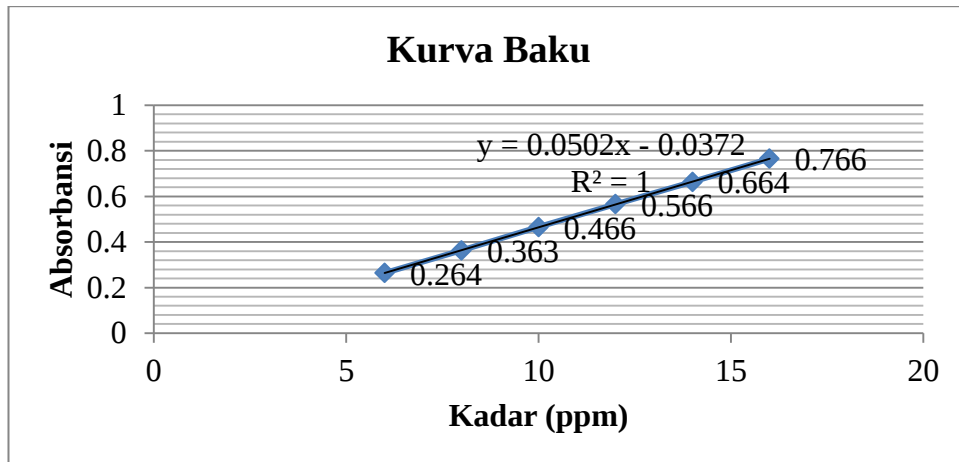
Wassalamu'alaikum Wr. Wb.

Semarang, Mei 2018
Kep. Bag. Farmasi Fisika & Farmasetika

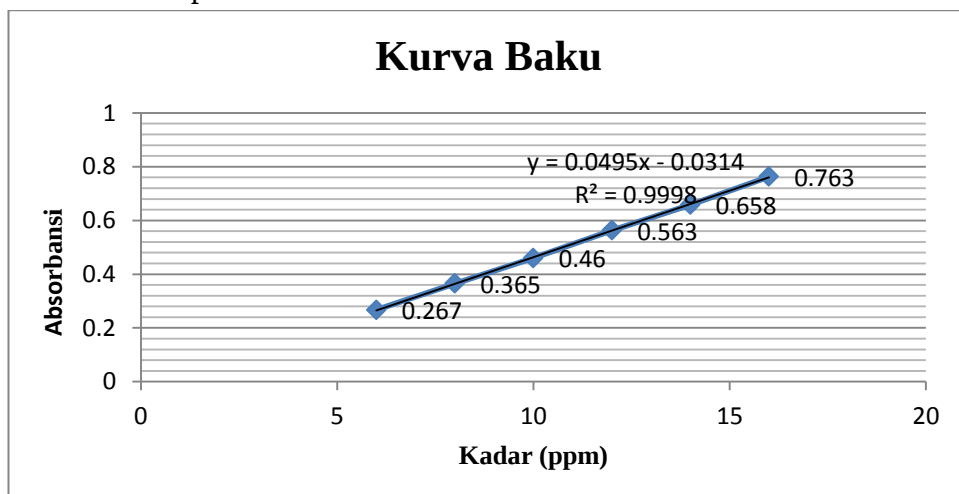
Etya Zuffa, M.Sc, Apt

Lampiran 15. Grafik hasil kurva baku

Kurva baku replikasi 1



Kurva baku replikasi 2



Kurva baku replikasi 3

