

LAMPIRAN

Lampiran 1. Surat Keterangan Laboratorium Farmasi Fisika



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. 03/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 : Mawarda Alistinafia N
NIM : 145010175
Fakultas : Farmasi

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

“Formulasi Film Transdermal Pravastatin Sodium Dengan Kombinasi Polimer Sodium Karboksimetil Selulosa (SCMC) dan Etil Selulosa (EC)”.

Demikian surat keterangan ini dibuat untuk dipergunakan semestinya.

Wassalamu'alaikum Wr. Wb.

Semarang, Mei 2018
Ka. Bag Farmasi Fisika & Farmasetika
Elva Zulfa, M.Sc, Apt



Lampiran 2. Certificate of Analysis Pravastatin Sodium



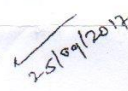
Biocon Limited
Biocon Special Economic Zone
Plot No. 2 - 4, Phase IV
Bommasandra-kgara Link Road
Bommasandra Pwd
Bangalore 560 099, India
T 91 80 7608 2808
F 91 80 2852 3423
www.biocon.com

CERTIFICATE OF ANALYSIS
QUALITY ASSURANCE

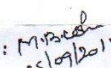
Product Name: PRAVASTATIN SODIUM Ph.Eur.	A.R.No. : 40000150934	Page No. : 1 of 2
Batch No./Disp. Ref. No. : BS17001406/BF17003921	Manufacturing date: July 2017	
Quantity : 3.00 kg	Expiry date : June 2020	

Ph. Eur. and In-house Specifications:

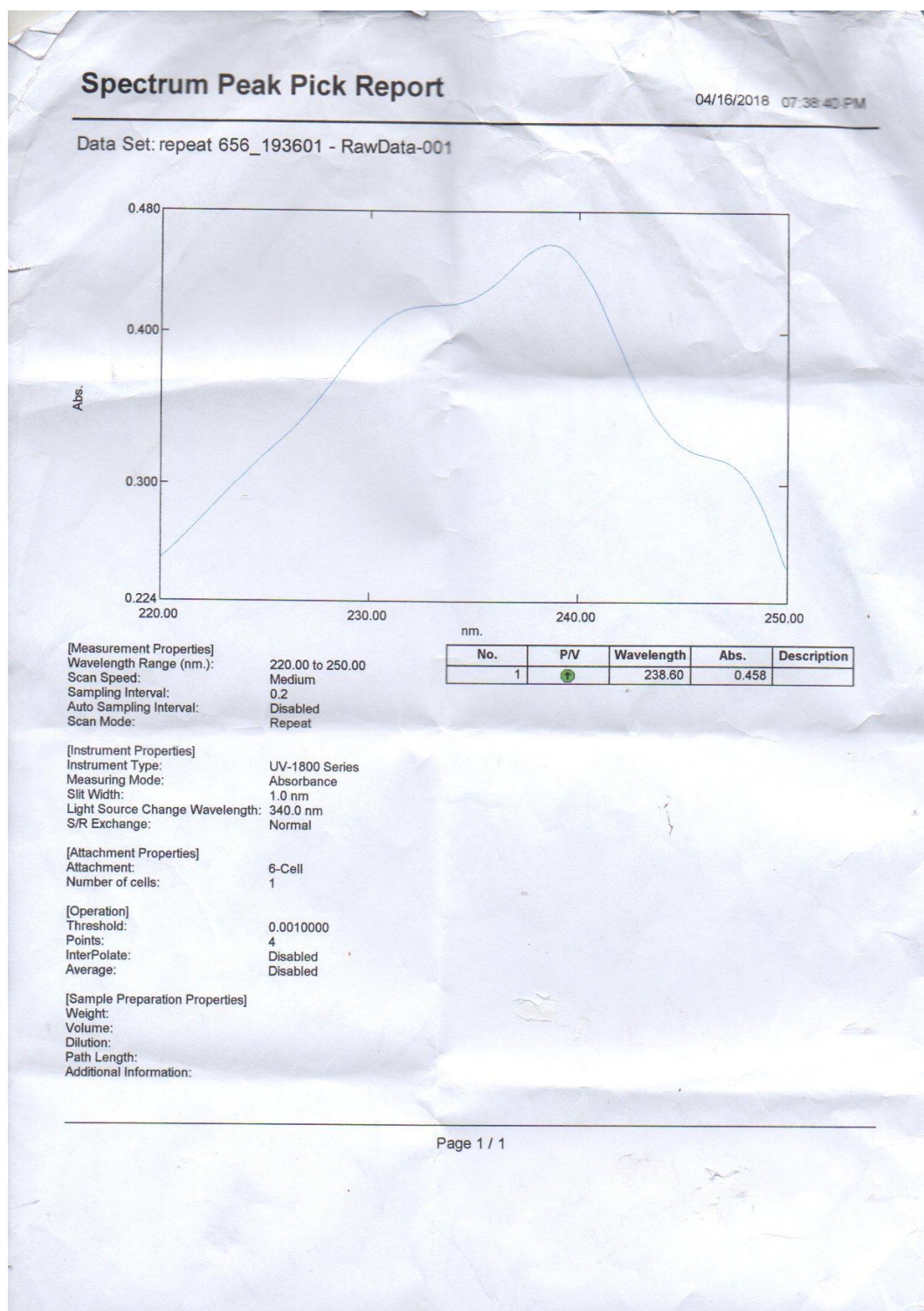
TESTS	OBSERVATIONS	LIMITS
Characters:		
a. Appearance	White crystalline powder, hygroscopic	a. White or yellowish white powder or crystalline powder, hygroscopic.
b. Solubility	Complies	b. Freely soluble in Water and in Methanol. Soluble in anhydrous ethanol.
Identification		
a. By SOR	Complies	a. It 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 $[\alpha]_D^{20}$, in water	+157°	Between +153° and +159°
Related substances (by HPLC)	Below disregard limit Not detected 0.076% Below disregard limit	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) - NMT 0.20% [3''-(S)-hydroxypravastatin] - NMT 0.15% Impurity G - NMT 0.15% Maximum individual unspecified impurity - NMT 0.10% Total impurities - NMT 0.60%
Ethanol 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 : 
 Date : 25/09/2017

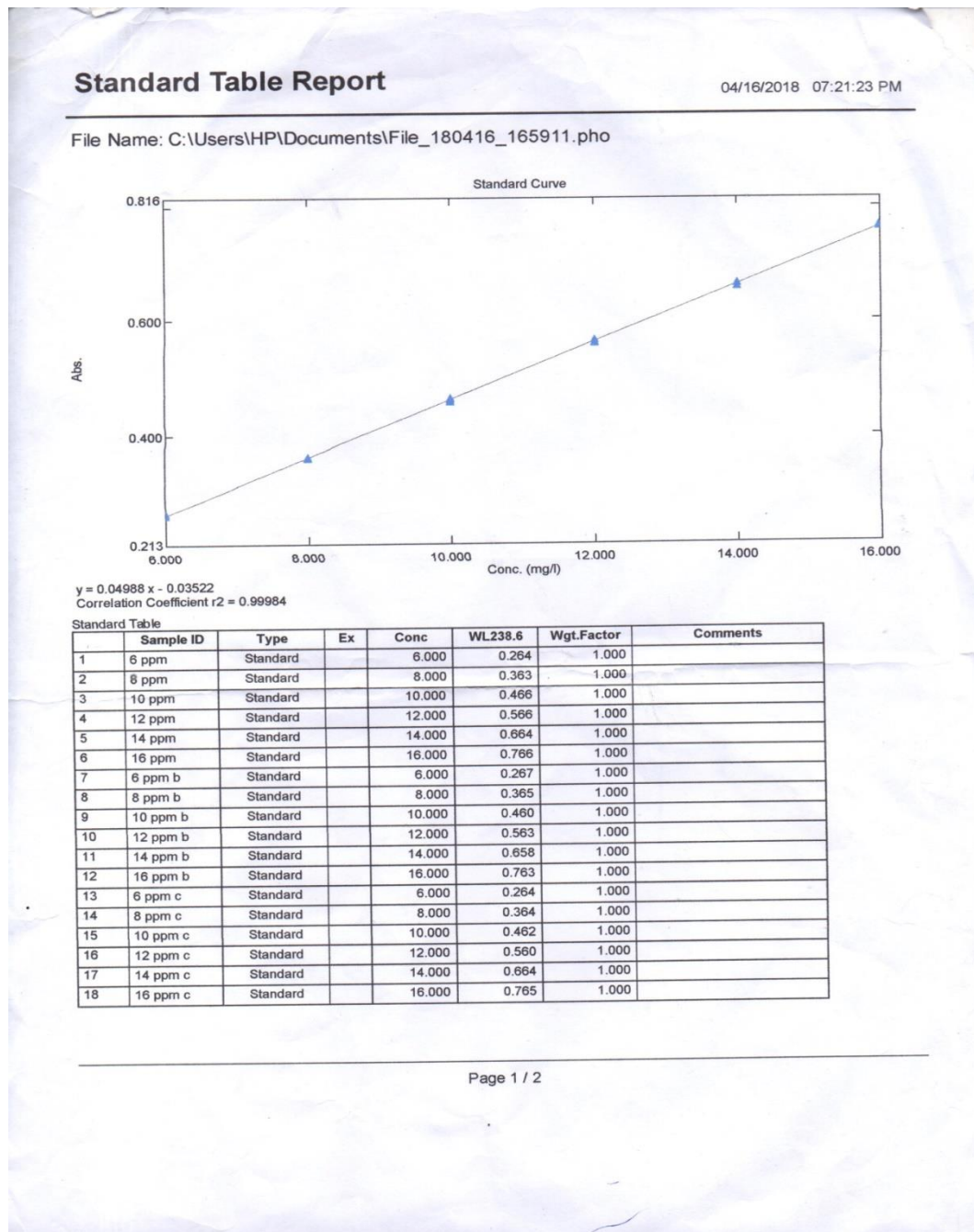
Checked by : 
 Date : 25/09/2017

Approved by : 
 Date : 25/09/2017
 (Quality Assurance)

Lampiran 3. Panjang gelombang Maksimal



Lampiran 4. Data Absorbansi Kurva Baku



Lampiran 5. Data Uji Keragaman Bobot

Replikasi	F1 7:3 (mg)	F2 8:2 (mg)	F3 9:1 (mg)
1	310.6	319.2	322.5
2	310.4	318.1	296.7
3	311	283	294
4	298.5	290	287.1
5	298.4	285	313.6
6	280.4	292.5	323.5
7	285	319.7	313.3
8	284.9	320.7	291.4
9	311.2	295	294.3
10	311.6	302.5	292.9
Rata-rata	300.2	302.57	302.93
SD	12.66272	15.44985	13.76251
CV	0.042181	0.051062	0.045431



Lampiran 6. Data Uji Ketebalan

Replikasi	F1 7:3 (cm)	F2 8:2 (cm)	F3 9:1 (cm)
1	0.024	0.024	0.026
2	0.022	0.022	0.022
3	0.022	0.024	0.022
Rata-rata	0.0227	0.0233	0.0233
SD	0.0011547	0.0011547	0.0011547



Lampiran 7. Data Uji Daya Tahan Lipat

Formula	Folding endurance
F1 7:3 (mg)	>800
	>800
	>800
F2 8:2 (mg)	>800
	>800
	>800
F3 9:1 (mg)	>800
	>800
	>800



Lampiran 8. Data Uji Penyerapan Lembab

Formula	Bobot awal (mg)	Bobot akhir (mg)	% moisture uptake	% rata-rata	SD
F1 7:3	280.4	304.7	8.67	8.02	0.59
	285	307.5	7.89		
	284.9	306.3	7.51		
F2 8:2	318.1	337.2	6.00	5.64	0.31
	319.7	337.3	5.50		
	320.7	338.1	5.42		
F3 9:1	348	365.2	4.94	5.46	0.46
	350	369.6	5.60		
	299.9	317.4	5.83		

% penyerapan lembab = $\frac{\text{bobot akhir} - \text{bobot awal}}{\text{Bobot awal}} \times 100$

Bobot awal



Lampiran 9. Data Uji Kandungan Zat Aktif

F1 7:3							
Absorbansi	Konsentrasi (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata (%)	SD	CV
0.413	8.97	40	358.87	89.72	87.72	1.738	0.02
0.397	8.65	40	346.11	86.53			
0.399	8.69	40	347.71	86.93			

F2 8:2							
Absorbansi	Konsentrasi (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata (%)	SD	CV
0.418	9.07	40	362.85	90.71	90.05	0.698	0.01
0.415	9.01	40	360.46	90.12			
0.411	8.93	40	357.27	89.32			

F3 9:1							
Absorbansi	Konsentrasi (ppm)	FP	Kadar (mg)	Recovery (%)	Rata-rata (%)	SD	CV
0.423	9.17	40	366.84	91.71	90.78	0.829	0.01
0.417	9.05	40	362.06	90.51			
0.415	9.01	40	360.46	90.12			

Perhitungan Kandungan zat aktif pravastatin sodium

Persamaan kurva baku - > $Y = 0.05018x - 0.0372$

Formula III replikasi 3 - > $0.415 = 0.05018x - 0.0372$

$$X = \frac{0.415 + 0.0372}{0.05018}$$

$$X = 9.01$$

$$X = 9.01$$

\Kadar pravastatin sodium = kadar (ppm) X FP

$$= 9.011 \text{ ppm} \times 40$$

$$= 360.46 \text{ mg}$$

Recovery = $\frac{\text{kadar pravastatin sodium (mg)}}{\text{Kadar pravastatin sodium sesungguhnya (mg)}} \times 100\%$

Kadar pravastatin sodium sesungguhnya (mg)

$$= \frac{360.46 \text{ mg}}{400 \text{ mg}} \times 100\% \rightarrow 90.12\%$$

$$400 \text{ mg}$$

Lampiran 10. Data Uji Disolusi *In Vitro*

FI (8:2)

Replikasi I

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.204	-	4.81	4.326	0	4.326	11.88
2	0.331	-	7.34	6.604	0.027	6.631	18.21
3	0.342	-	7.56	6.801	0.067	6.869	18.21
4	0.426	-	9.23	8.308	0.109	8.417	23.11
5	0.48	-	10.31	9.276	0.161	9.437	25.91
6	0.512	-	10.94	9.850	0.218	10.068	27.64

Replikasi II

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.272	-	6.16	5.546	0	5.546	14.90
2	0.302	-	6.76	6.084	0.034	6.118	16.44
3	0.326	-	7.24	6.514	0.072	6.586	17.70
4	0.363	-	7.98	7.178	0.112	7.290	19.59
5	0.411	-	8.93	8.039	0.156	8.195	22.02
6	0.453	-	9.77	8.792	0.206	8.998	24.18

Replikasi III

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.277	-	6.26	5.635	0	5.635	15.50
2	0.296	-	6.64	5.976	0.035	6.011	16.54
3	0.308	-	6.88	6.191	0.072	6.263	17.23
4	0.387	-	8.45	7.608	0.110	7.718	21.23
5	0.408	-	8.87	7.985	0.157	8.142	22.40
6	0.452	-	9.75	8.774	0.206	8.980	24.70

FII (7:3)

Replikasi I

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.112	-	2.97	2.676	0	2.676	7.03
2	0.118	-	3.09	2.784	0.017	2.800	7.36
3	0.120	-	3.13	2.819	0.034	2.853	7.50
4	0.308	-	6.88	6.191	0.051	6.242	16.40
5	0.313	-	6.98	6.281	0.089	6.370	16.74
6	0.345	-	7.62	6.855	0.128	6.983	18.35

Replikasi II

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.200	-	4.73	4.254	0	4.254	11.14
2	0.315	-	7.02	6.317	0.026	6.343	16.61
3	0.322	-	7.16	6.442	0.065	6.508	17.04
4	0.351	-	7.74	6.963	0.105	7.068	18.51
5	0.360	-	7.92	7.124	0.148	7.272	19.05
6	0.380	-	8.31	7.483	0.192	7.675	20.10

Replikasi III

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.185	-	4.43	3.985	0	3.985	11.44
2	0.193	-	4.59	4.129	0.025	4.153	11.93
3	0.228	-	5.28	4.756	0.050	4.807	13.80
4	0.259	-	5.90	5.312	0.079	5.392	15.48
5	0.266	-	6.04	5.438	0.112	5.550	15.94
6	0.283	-	6.38	5.743	0.146	5.889	16.91

FIII (6:4)

Replikasi I

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.204	-	4.81	4.326	0	4.326	11.52
2	0.219	-	5.11	4.595	0.027	4.622	12.31
3	0.245	-	5.62	5.061	0.055	5.116	13.62
4	0.271	-	6.14	5.528	0.086	5.614	14.95
5	0.289	-	6.50	5.851	0.120	5.971	15.90
6	0.297	-	6.66	5.994	0.157	6.151	16.38

Replikasi II

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.209	-	4.91	4.416	0	4.416	11.39
2	0.217	-	5.07	4.559	0.027	4.586	11.82
3	0.251	-	5.74	5.169	0.055	5.224	13.47
4	0.292	-	6.56	5.904	0.087	5.992	15.45
5	0.310	-	6.92	6.227	0.124	6.351	16.38
6	0.343	-	7.58	6.819	0.162	6.981	18.00

Replikasi III

Waktu (jam)	Absorbansi	Faktor Pengenceran	Kadar ($\mu\text{g/ml}$)	Σ Terlarut	Faktor Koreksi	Σ Terlarut setelah koreksi	%Terlarut
1	0.194	-	4.59	4.131	0	4.131	10.68
2	0.228	-	5.28	4.752	0.026	4.778	12.36
3	0.245	-	5.62	5.058	0.055	5.113	13.22
4	0.265	-	6.02	5.418	0.086	5.504	14.24
5	0.297	-	6.66	5.994	0.120	6.114	15.81
6	0.312	-	6.96	6.264	0.157	6.421	16.61

Kadar ($\mu\text{g/ml}$) diperoleh dengan memasukkan absorbansi pada persamaan kurva baku ($Y = 0.05018x + 0.0372$). Absorbansi pada jam ke-1 yaitu 0.194 diperoleh hasil $x = 4.59 \mu\text{g/ml}$ dikalikan faktor pengenceran $x = 4.59 \mu\text{g/ml}$

Σ Terlarut diperoleh dari kadar dikalikan volume medium yang digunakan. Kadar pada jam ke-1 yaitu $4.59 \mu\text{g/ml}$ dikalikan 900 ml, hasilnya 4.131 mg

Faktor Koreksi diperoleh dari $(5/900 \times \text{kadar sebelumnya}) + \text{faktor koreksi sebelumnya}$. Faktor koreksi pada jam ke-2 diperoleh dari $(5/900 \times 0) + 0 = 0$

Σ Terlarut setelah koreksi diperoleh dari $=(\text{faktor koreksi} + \Sigma \text{ Terlarut})$

%Terlarut diperoleh dari $=(\Sigma \text{ Terlarut setelah koreksi} / (\text{bobot film} / \text{bobot rata-rata film} \times \% \text{rata-rata kandungan zat aktif} \times \text{kadar awal dalam film})) \times 100\%$

Lampiran 11. Hasil SPSS Keragaman Bobot

Test of Homogeneity of Variances**Keseragaman Bobot**

Levene Statistic	df1	df2	Sig.
.610	2	27	.551

Tests of Normality

Formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Keseragaman Bobot F1	.290	10	.017	.806	10	.017
F2	.243	10	.098	.851	10	.059
F3	.275	10	.031	.848	10	.055

a. Lilliefors Significance Correction

Kruskal-Wallis**Ranks**

	Formula	N	Mean Rank
Keseragaman Bobot	F1	10	13.95
	F2	10	15.85
	F3	10	16.70
	Total	30	

Test Statistics^{a,b}

	Keseragaman Bobot
Chi-Square	.512
df	2
Asymp. Sig.	.774

a. Kruskal Wallis Test

b. Grouping Variable: Formula

Lampiran 12. Hasil SPSS Uji Ketebalan

Test of Homogeneity of Variances

uji ketebalan

Levene Statistic	df1	df2	Sig.
7.813	2	5	.029

Tests of Normality

formula		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
uji ketebalan	F1	.385	3	.	.750	3	.000
	F2	.385	3	.	.750	3	.000
	F3	.385	3	.	.750	3	.000

a. Lilliefors Significance Correction

Kruskal-Wallis**Ranks**

for...	N	Mean Rank
uji ketebalan F1	3	4.33
F2	3	5.67
F3	3	5.00
Total	9	

Test Statistics^{a,b}

	uji ketebalan
Chi-Square	.444
df	2
Asymp. Sig.	.801

a. Kruskal Wallis Test

b. Grouping Variable: formula

Lampiran 13. Hasil SPSS Uji Penyerapan Lembab

Test of Homogeneity of Variances

Penyerapan Lembab

Levene Statistic	df1	df2	Sig.
.157	2	6	.858

Tests of Normality

formula		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Penyerapan Lembab	f1	.256	3	.	.962	3	.625
	f2	.203	3	.	.994	3	.849
	f3	.288	3	.	.928	3	.480

a. Lilliefors Significance Correction

ANOVA

Penyerapan Lembab

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	12.940	2	6.470	24.564	.001
Within Groups	1.580	6	.263		
Total	14.521	8			

Multiple Comparisons

Penyerapan Lembab
Tukey HSD

(I) formula	(J) formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
f1	f2	2.52000 [*]	.41905	.002	1.2343	3.8057
	f3	2.56667 [*]	.41905	.002	1.2809	3.8524
f2	f1	-2.52000 [*]	.41905	.002	-3.8057	-1.2343
	f3	.04667	.41905	.993	-1.2391	1.3324
f3	f1	-2.56667 [*]	.41905	.002	-3.8524	-1.2809
	f2	-.04667	.41905	.993	-1.3324	1.2391

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

Lampiran 14. Hasil SPSS Uji Kandungan Zat Aktif

Tests of Normality

	Formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Kandungan zat aktif	f1	.344	3	.	.842	3	.219
	f2	.204	3	.	.993	3	.843
	f3	.292	3	.	.923	3	.463

a. Lilliefors Significance Correction

Test of Homogeneity of Variances

Kandungan zat aktif

Levene Statistic	df1	df2	Sig.
3.008	2	5	.139

ANOVA

Kandungan zat aktif

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	15.717	2	7.859	5.020	.064
Within Groups	7.827	5	1.565		
Total	23.544	7			



Lampiran 15. Hasil SPSS Uji Disolusi *In Vitro*

Tests of Normality

Formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
% Terlarut F1	.248	6	.200 [*]	.911	6	.444
F2	.142	6	.200 [*]	.963	6	.844
F3	.177	6	.200 [*]	.970	6	.892

a. Lilliefors Significance Correction

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

Test of Homogeneity of Variances

% Terlarut			
Levene Statistic	df1	df2	Sig.
2.138	2	15	.152

ANOVA

% Terlarut					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	90.653	2	45.326	4.470	.030
Within Groups	152.089	15	10.139		
Total	242.742	17			

Multiple Comparisons

% Terlarut
Tukey HSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
F1	F2	4.80333 [*]	1.83841	.049	.0281	9.5786
	F3	4.71667	1.83841	.053	-.0586	9.4919
F2	F1	-4.80333 [*]	1.83841	.049	-9.5786	-.0281
	F3	-.08667	1.83841	.999	-4.8619	4.6886
F3	F1	-4.71667	1.83841	.053	-9.4919	.0586
	F2	.08667	1.83841	.999	-4.6886	4.8619

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