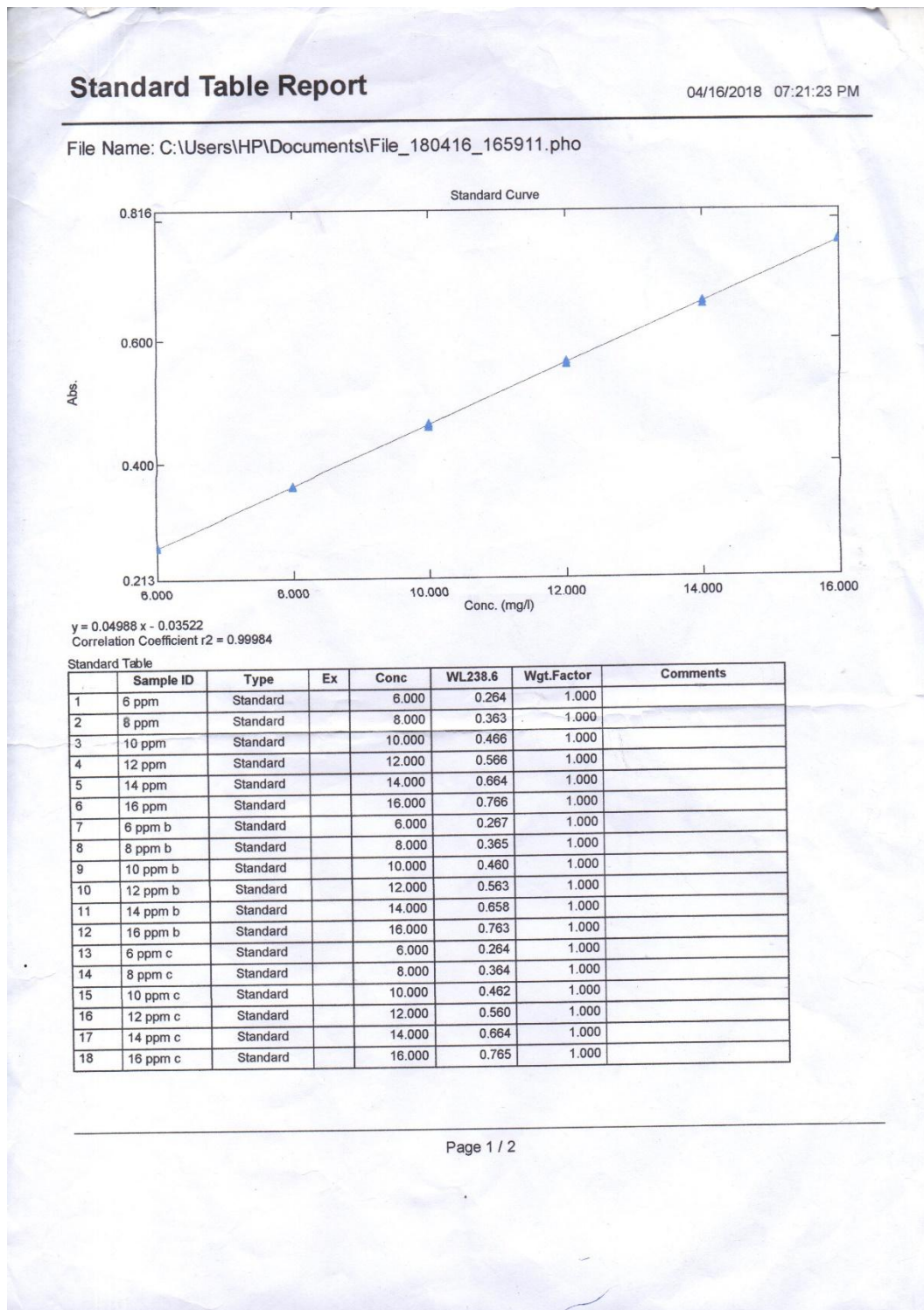
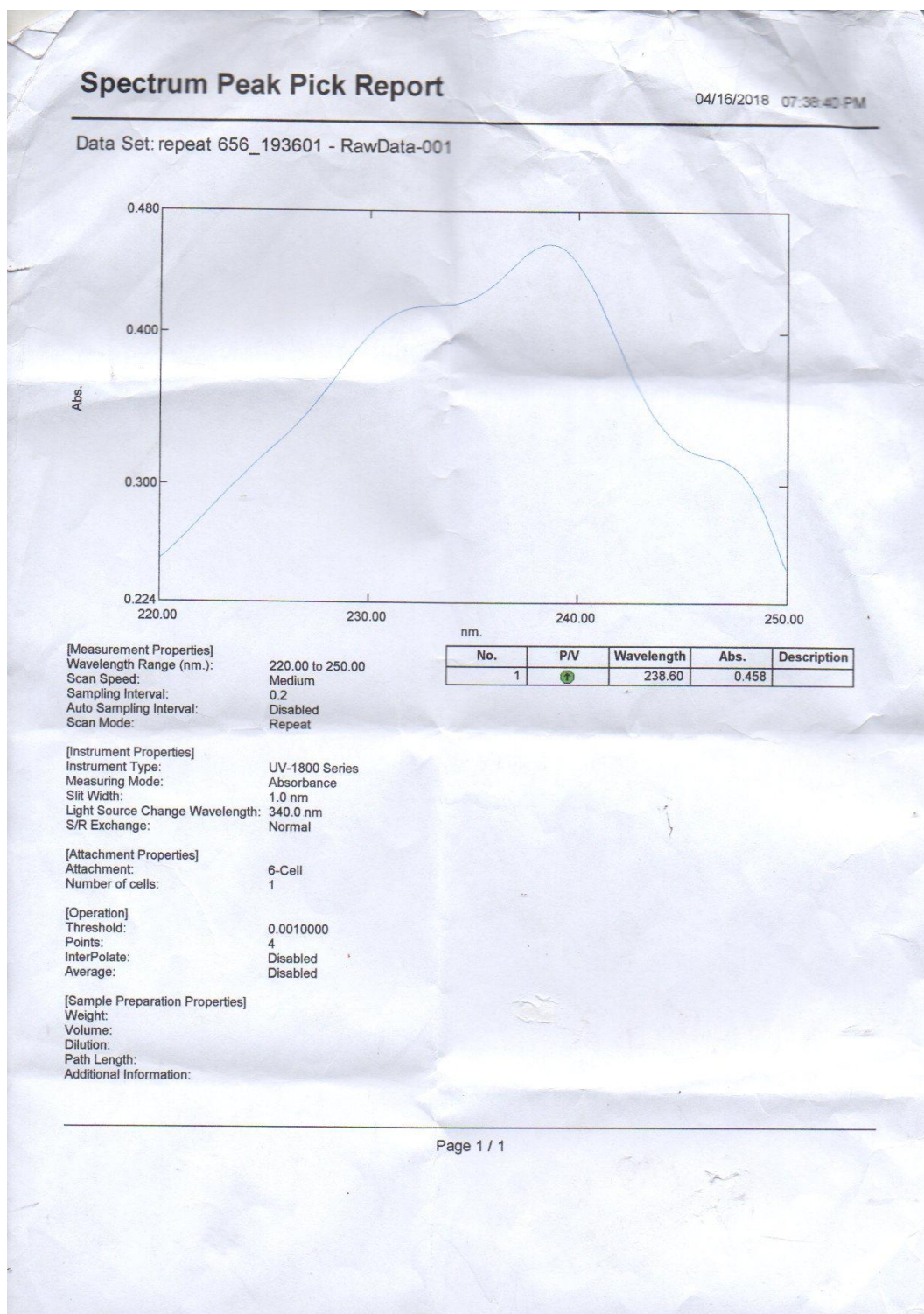



Lampiran 1. Data Absorbansi Kurva Baku



Lampiran 2. Panjang Gelombang Maksimal



Lampiran 3. Sertifikat Analisis Pravastatin Sodium



Biocon Limited
 Biocon Special Economic Zone
 Plot Nos. 2 - 4, Phase IV
 Bommasandra-Jigani Link Road
 Bommasandra Pali
 Bangalore 560 099, India
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 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 b. Solubility	White crystalline powder, hygroscopic Complies	a. White or yellowish white powder or crystalline powder, hygroscopic. b. Freely soluble in Water and in Methanol. Soluble in anhydrous ethanol.
Identification a. By SOR b. By IR Absorption c. By test for Sodium	Complies Complies Complies	a. It complies with test for specific optical rotation. b. IR spectrum of sample matches with the Ph.Eur. Reference spectrum of Pravastatin sodium. 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) [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

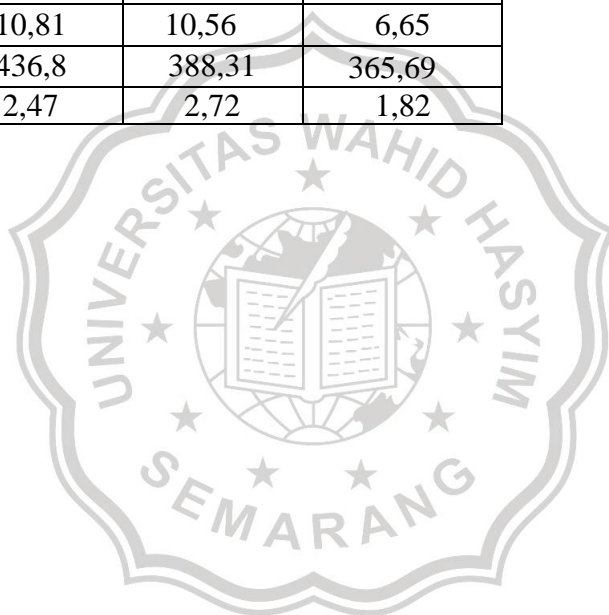
Prepared by : *[Signature]* Date : 25/09/2017

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

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

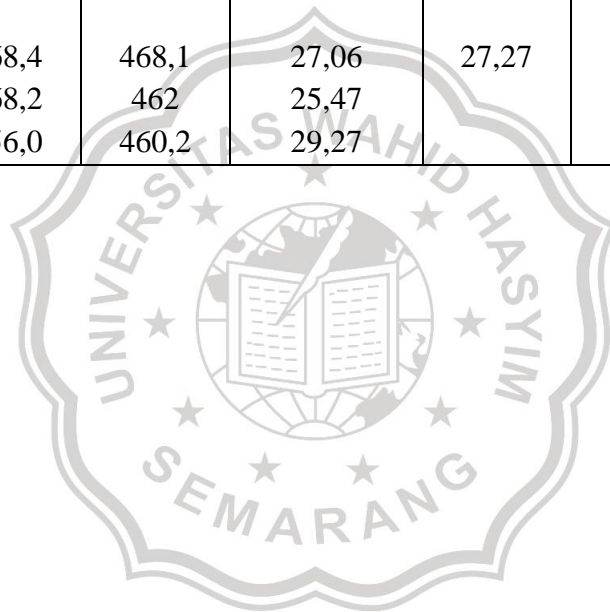
Lampiran 4. Uji Keseragaman Bobot

Replikasi	Formula I (mg)	Formula II (mg)	Formula III (mg)
1	426	399	368,4
2	441	377,9	368,2
3	453,5	385	365,6
4	435,1	377	368
5	446	380,4	369
6	428,9	378,7	363
7	431	409,4	354,8
8	427,7	391,2	372,3
9	426	390,9	373,6
10	452,8	393,6	354
SD	10,81	10,56	6,65
Rata-rata	436,8	388,31	365,69
RSD	2,47	2,72	1,82



Lampiran 5. Uji Penyerapan Lembab

Formula	Bobot Awal (mg)	Bobot Akhir (mg)	% Penyerapan Lembab	Rata-Rata	SD	RSD
FI						
1	431,0	548	27,15	29,21	1,94	6,66
2	441,0	571,1	29,50			
3	435,1	570	31,00			
FII						
1	391,2	509,9	30,34	28,38	2,00	7,07
2	390,0	492,7	26,33			
3	393,6	505,6	28,46			
FIII						
1	368,4	468,1	27,06	27,27	1,90	6,99
2	368,2	462	25,47			
3	356,0	460,2	29,27			



Lampiran 6. Uji Ketebalan

Replikasi	FI	FII	FIII
1	0,22	0,22	0,22
2	0,22	0,22	0,22
3	0,22	0,22	0,22
SD	0	0	0
Rata-rata	0,22	0,22	0,22
RSD	0%	0%	0%



Lampiran 7. Uji Daya Tahan Lipat

Formula	Replikasi	Daya Tahan Lipat
FI	1	150
	2	150
	3	150
FII	1	1000
	2	1150
	3	1000
FIII	1	1500
	2	1500
	3	1500



Lampiran 8. Uji Kandungan Zat Aktif

F1								
Abs	Fp	Kadar (µg/ml)	Kadar (mg)	Kadar pravastatin sodium	% recovery	Rata-rata	SD	RSD
0,467	40	10,05	40,19	400	100,47	95,75	5,12	5,35
0,447	40	9,65	38,59	400	96,48			
0,416	40	9,03	36,12	400	90,31			

FII								
Abs	Fp	Kadar (µg/ml)	Kadar (mg)	Kadar pravastatin sodium	% recovery	Rata-rata	SD	RSD
0,438	40	9,47	37,88	400	94,69	94,16	0,75	0,80
0,431	40	9,33	37,32	400	93,30			
0,437	40	9,45	37,80	400	94,49			

FIII								
Abs	Fp	Kadar (µg/ml)	Kadar (mg)	Kadar pravastatin sodium	% recovery	Rata-rata	SD	RSD
0,411	40	8,93	35,72	400	89,31	88,11	1,44	1,63
0,397	40	8,65	34,61	400	86,52			
0,407	40	8,85	35,41	400	88,51			

Lampiran 9. Uji Disolusi

Formula I PVP replikasi 1						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,259	5,90	5312,03	0	5,31	14,17
2	0,3	6,72	6047,30	29,51	6,08	16,20
3	0,363	7,97	7177,11	63,11	7,24	19,31
4	0,399	8,69	7822,71	102,98	7,93	21,14
5	0,472	10,15	9131,85	146,44	9,28	24,74
6	0,514	10,98	9885,05	197,17	10,08	26,89

Formula I PVP replikasi 2						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,205	4,83	4343,63	0	4,34	11,49
2	0,238	5,48	4935,43	24,13	4,96	13,12
3	0,259	5,90	5312,03	51,55	5,36	14,19
4	0,303	6,78	6101,10	81,06	6,18	16,36
5	0,343	7,58	6818,44	114,96	6,93	18,35
6	0,407	8,86	7966,18	152,84	8,12	21,48

Formula I PVP replikasi 3						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,203	4,79	4307,76	0	4,31	11,29
2	0,246	5,64	5078,90	23,93	5,10	13,38
3	0,269	6,10	5491,37	52,15	5,54	14,53
4	0,317	7,06	6352,17	82,66	6,43	16,87
5	0,348	7,68	6908,10	117,95	7,03	18,42
6	0,401	8,73	7858,58	156,32	8,01	21,01

Formula II PVP replikasi 1						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,22	5,13	4612,63	0	4,61	12,62
2	0,232	5,36	4827,83	25,66	4,8	13,28
3	0,261	5,94	5347,90	52,45	5,40	14,78
4	0,317	7,058	6352,17	82,16	6,43	17,60
5	0,337	7,46	6710,84	117,45	6,83	18,68
6	0,377	8,25	7428,17	154,73	7,58	20,74

Formula II PVP replikasi 2						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,212	4,97	4469,16	0	4,47	12,17
2	0,232	5,36	4827,83	24,83	4,86	13,21
3	0,24	5,52	4971,39	51,65	5,02	13,68
4	0,288	6,48	5832,10	79,27	5,91	16,09
5	0,312	6,96	6262,50	111,67	6,37	17,35
6	0,343	7,58	6818,44	146,46	6,96	18,96

Formula II PVP replikasi 3						
Jam	Abs	Kadar (µg/ml)	Jumlah Terlarut (µg)	Koreksi (µg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,221	5,15	4630,56	0	4,63	12,63
2	0,232	5,37	4827,83	25,73	4,85	13,24
3	0,245	5,62	5060,97	52,55	5,11	13,95
4	0,293	6,58	5921,77	80,66	6,00	16,38
5	0,316	7,04	6334,24	113,56	6,45	17,59
6	0,344	7,60	6836,37	148,75	6,99	19,06

Formula III PVP replikasi 1						
Jam	Abs	Kadar ($\mu\text{g/ml}$)	Jumlah Terlarut (μg)	Koreksi (μg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,124	3,21	2891,02	0	2,89	8,15
2	0,149	3,71	3339,36	16,06	3,36	9,45
3	0,158	3,89	3500,76	34,61	3,54	9,96
4	0,189	4,51	4056,70	54,06	4,11	11,58
5	0,203	4,79	4307,76	76,60	4,38	12,35
6	0,278	6,28	5652,77	100,53	5,75	16,21

Formula III PVP replikasi 2						
Jam	Abs	Kadar ($\mu\text{g/ml}$)	Jumlah Terlarut (μg)	Koreksi (μg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,109	2,91	2622,02	0	2,62	7,44
2	0,137	3,47	3124,16	14,57	3,14	8,90
3	0,166	4,05	3644,23	31,92	3,68	10,43
4	0,179	4,31	3877,36	52,17	3,93	11,15
5	0,284	6,40	5760,37	73,71	5,83	16,55
6	0,299	6,70	6029,37	105,71	6,14	17,40

Formula III PVP replikasi 3						
Jam	Abs	Kadar ($\mu\text{g/ml}$)	Jumlah Terlarut (μg)	Koreksi (μg)	Jumlah terlarut setelah dikoreksi (mg)	% terlarut
1	0,126	3,25	2926,89	0	2,93	8,36
2	0,141	3,55	3195,89	16,26	3,21	9,18
3	0,154	3,81	3429,03	34,01	3,46	9,90
4	0,182	4,37	3931,16	53,07	3,98	11,39
5	0,213	4,99	4487,10	74,91	4,56	13,04
6	0,265	6,02	5419,63	99,83	5,52	15,78

Lampiran 10. Hasil SPSS Uji Keseragaman Bobot

Tests of Normality

formula		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
keseragaman bobot	formula1	.204	10	.200 [*]	.865	10	.087
	formula2	.173	10	.200 [*]	.913	10	.305
	formula3	.236	10	.122	.871	10	.104

a. Lilliefors Significance Correction

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

Test of Homogeneity of Variances

keseragaman bobot

Levene Statistic	df1	df2	Sig.
2.131	2	27	.138

ANOVA

keseragaman bobot

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	26398.589	2	13199.294	145.156	.000
Within Groups	2455.158	27	90.932		
Total	28853.747	29			

Multiple Comparisons

keseragaman bobot

Tukey HSD

(I) formula (J) formula		Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
formula1	formula2	51.5100 [*]	2.3967	.000	45.568	57.452
	formula3	72.5900 [*]	2.3967	.000	66.648	78.532
formula2	formula1	-51.5100 [*]	2.3967	.000	-57.452	-45.568
	formula3	21.0800 [*]	2.3967	.000	15.138	27.022
formula3	formula1	-72.5900 [*]	2.3967	.000	-78.532	-66.648
	formula2	-21.0800 [*]	2.3967	.000	-27.022	-15.138

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

Lampiran 11. Hasil SPSS Uji Daya Tahan Lipat

Tests of Normality^{b,c}

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
dayatahanlipat f2	.219	3	.	.987	3	.780

a. Lilliefors Significance Correction

b. dayatahanlipat is constant when formula = f1. It has been omitted.

c. dayatahanlipat is constant when formula = f3. It has been omitted.

Test of Homogeneity of Variances

dayatahanlipat

Levene Statistic	df1	df2	Sig.
5.953	2	6	.038

Test Statistics^{a,p}

	dayatahanlipat
Chi-Square	7.784
df	2
Asymp. Sig.	.020

a. Kruskal Wallis Test

b. Grouping Variable: formula

Test Statistics^p

	dayatahanlipat
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 12. Hasil SPSS Uji Peyerapan Kelembaban

Tests of Normality

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
penyerapan lembab formula 1	.225	3	.	.984	3	.758
formula 2	.183	3	.	.999	3	.931
formula 3	.211	3	.	.991	3	.817

a. Lilliefors Significance Correction

Test of Homogeneity of Variances

penyerapan lembab

Levene Statistic	df1	df2	Sig.
.002	2	6	.998

ANOVA

penyerapan lembab

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	5.720	2	2.860	.752	.511
Within Groups	22.830	6	3.805		
Total	28.550	8			

Lampiran 13 Hasil SPSS Uji Kandungan Zat Aktif

Tests of Normality

formul a	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
kandungan zat aktif 1	.223	3	.	.985	3	.763
2	.334	3	.	.859	3	.264
3	.260	2	.			

a. Lilliefors Significance Correction

Test of Homogeneity of Variances

kandungan zat aktif

Levene Statistic	df1	df2	Sig.
3.527	2	6	.097

ANOVA

kandungan zat aktif

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	98.571	2	49.285	5.059	.052
Within Groups	58.458	6	9.743		
Total	157.029	8			

Lampiran 14. Hasil SPSS Uji Disolusi Obat secara *In Vitro*

ANOVA

persenterlarut	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	111.503	2	55.752	5.008	.022
Within Groups	166.998	15	11.133		
Total	278.502	17			

Tests of Normality

formula	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
persenterlarut formula 1	.144	6	.200*	.971	6	.901
formula 2	.207	6	.200*	.937	6	.634
formula 3	.184	6	.200*	.946	6	.708

a. Lilliefors Significance Correction

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

Test of Homogeneity of Variance

persenterlarut	Levene Statistic	df1	df2	Sig.
Based on Mean	.399	2	15	.678
Based on Median	.362	2	15	.703
Based on Median and with adjusted df	.362	2	12.798	.704
Based on trimmed mean	.403	2	15	.676

Multiple Comparisons

persenterlarut
Tukey HSD

(I) formula	(J) formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
formula 1	formula 2	1.78833	1.92641	.631	-3.2155	6.7921
	formula 3	5.94167	1.92641	.019	.9379	10.9455
formula 2	formula 1	-1.78833	1.92641	.631	-6.7921	3.2155
	formula 3	4.15333	1.92641	.112	-.8505	9.1571
formula 3	formula 1	-5.94167	1.92641	.019	-10.9455	-.9379
	formula 2	-4.15333	1.92641	.112	-9.1571	.8505

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