

BAB V
KESIMPULAN DAN SARAN

A. Kesimpulan

Berdasarkan hasil penelitian dapat disimpulkan bahwa :

1. Mutu fisik dan profil disolusi dari sediaan tablet glibenklamid merk dagang dan generik memenuhi persyaratan standar kontrol kualitas tablet yang baik.
2. Sediaan tablet glibenklamid merk dagang dan generik menghasilkan profil disolusi yang mirip yang ditunjukkan dengan nilai F2 50 - 100.

B. Saran

Saran dari hasil penelitian ini adalah :

1. Tablet glibenklamid generik memenuhi persyaratan standar yang sudah ditetapkan sehingga memiliki kualitas yang tidak jauh berbeda dengan tablet glibenklamid merk dagang, tidak salahnya mulai beralih menggunakan tablet glibenklamid generik yang harganya lebih terjangkau.
2. Perlu dilakukan penelitian uji bioekivalensi tablet glibenklamid merk dagang dan generik terhadap manusia sehingga mencerminkan keadaan sebenarnya dalam tubuh makhluk hidup.

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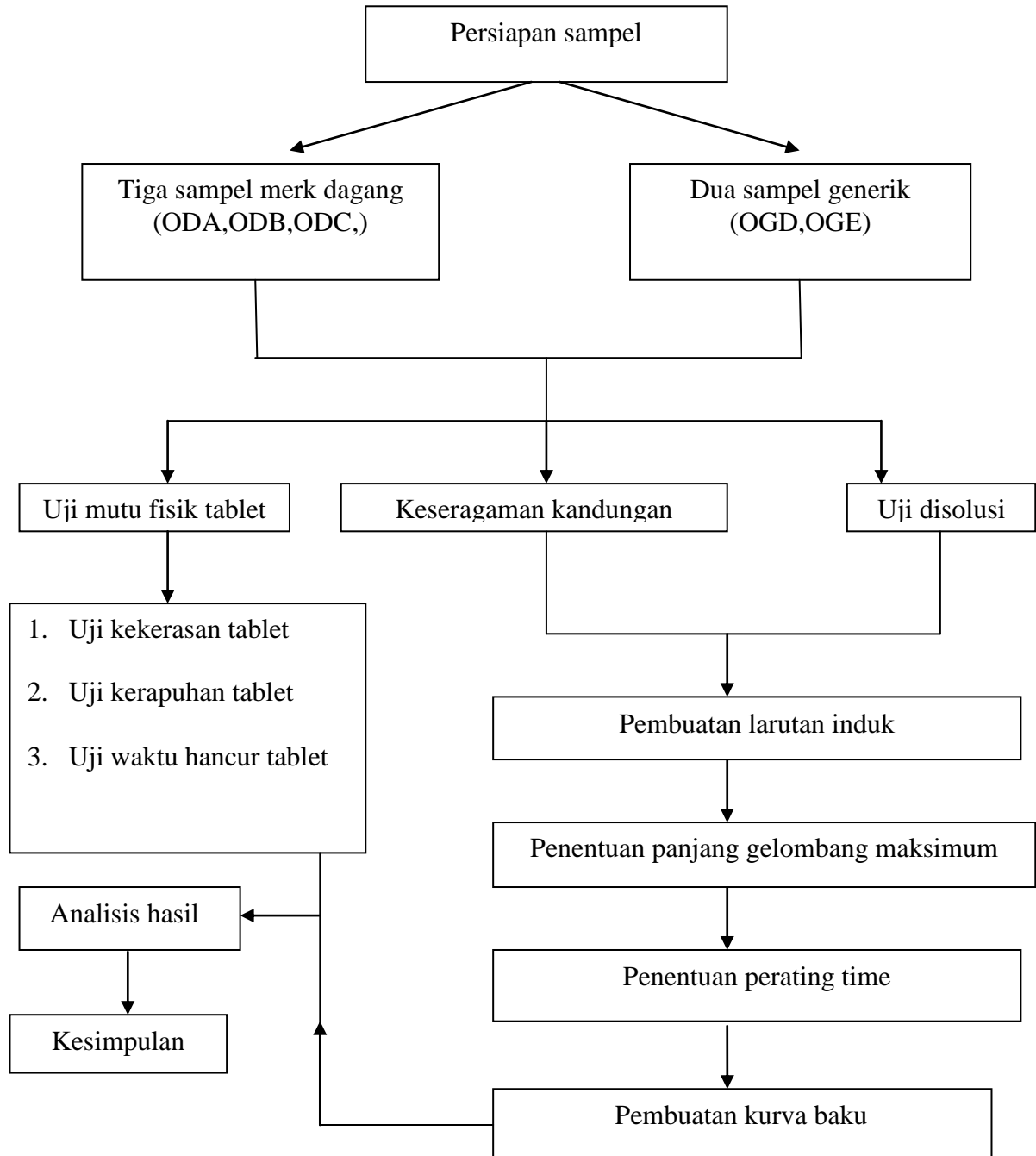
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Lampiran 1. Skema jalannya penelitian

Lampiran 2. Surat keterangan bantuan bahan

 **PT IFARS PHARMACEUTICAL LABORATORIES**
Jl. Raya Solo - Sragen Km. 14,9 Karanganyar - Solo 57762 INDONESIA
Telp. (0271) 8200888 (Hunting) Fax. (0271) 656230
email : general@ifars.co.id website : www.ifars.co.id

Nomor : IF/III/2014/21.020/040
Lamp. : 1 lembar
Hal : Bahan baku Glibenclamide

Surakarta, 22 Maret 2014


Kepada Yth. :
Dekan Fakultas Farmasi
Universitas Setia Budi
Jl. Let. Jend. Sutoyo
Solo 57127

Dengan hormat,

Bersama ini kami kirimkan bahan baku Glibenclamide sebanyak 1 g (satu gram) beserta foto copy Certificate of Analysis untuk mahasiswa atas nama Uvita Rahmawati (16102990 A) sebagaimana tercantum dalam surat saudara nomor : 879/A10-4/07.03.2014 pada tanggal 07 Maret 2014.

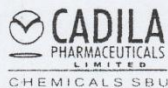
Demikian agar dapat diterima dan diteruskan kepada mahasiswa yang bersangkutan.

Hormat kami,
PT IFARS Pharmaceutical Laboratories
Penanggung Jawab Produksi


PT IFARS
PHARMACEUTICAL LABORATORIES
SURAKARTA - INDONESIA

Dra. Agustini, Apt.

Lampiran 3. Sertifikat analisis glibenklamid



3203, G.I.D.C., Estate,
Ankleshwar - 393 002.
Gujarat, India.

Phone : +91-2646 - 250174 / 220178
Fax : +91-2646 - 226519
Website : www.cadilapharma.com

Name of Finished Product		Glibenclamide BP/ Ph.Eur.	
Manufactured By		Cadila Pharmaceuticals Limited, Ankleshwar	
Batch. No.	13GLB061	A.R.NO.	FP130190
Manufacturing Date	OCTOBER 2013	Qty. Mfgd.	108.10 kg.
Expiry Date	SEPTEMBER 2018	Sample Qty	100 gm
Specification No.	FPS/027/02		
Storage Condition	Store in well-closed container, protect from light.		
Certificate of Analysis			
Test	Requirements	Results	
Characteristics Appearance	A white or almost white crystalline powder	White crystalline powder.	
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in alcohol and in methanol.	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in alcohol and in methanol.	
Identification A) Melting point C) By IR	Melting Point : 169°C to 174°C Examine by infrared absorption spectrophotometry, comparing with the spectrum obtained with Glibenclamide working standard. Examine the substance as cisc prepared using potassium bromide. If the spectra obtained shows differences, moisten separately the substance with methanol, triturate, dry at 100°C to 105°C and record the spectrum again.	171.1°C Matches with working standard.	
Related substances (By HPLC) 1. Impurity A 2. Impurity B 3. Unknown Impurity 1 4. Unknown Impurity 2 5. Unknown Impurity 3 6. Total of other Impurity	Not more than 0.5 %. Not more than 0.5 %. Not more than 0.2 %. Not more than 0.1 %. Not more than 0.1 %. Not more than 0.5 %.	0.02 % 0.02 % 0.03 % 0.01 % Not Detected 0.04 %	
Heavy metals	Not more than 20 ppm. (Determined on 1.0 g.)	Less than 20 ppm	
Loss on drying	Not more than 1.0 %. (Determined on 1.0 g by drying in an oven at 100 to 105°C.)	0.42 % w/w	
Sulphated ash	Not more than 0.1 % (Determined on 1.0 g.)	0.08 % w/w	
Assay	Not less than 99.0 % and not more than the equivalent of 101.0 % of C ₁₃ H ₁₈ ClN ₂ O ₆ S, calculated with reference to the dried substance.	99.2 % w/w	
Additional tests:			
Particle size (By Malvern master size)	For Information	90 % particles are less than 6.31 µ.	
Remarks: The material complies with respect to the BP-2012 Specification.			
Prepared By:		Checked By	
Date	16.11.13	Date	16.11.13
		Approved By	
		Date	16.11.13

F/QC029/01/20.02.13

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The Care Continues...

Lampiran 4. Hasil pemeriksaan kekerasan tablet

No	Kekerasan (Kg)				
	ODA	ODB	ODC	OGD	OGE
1	6,9	6,5	8	6	11,3
2	6,9	6,4	8,1	6,3	10,5
3	6,8	6	8	6,3	11,8
4	6,9	6	8	6,5	10,5
5	6,6	6,7	8,5	6	11,8
6	6,7	6	8,7	6	10,5
7	6,7	7	8,4	6	10,4
8	6,9	6,2	8	6,2	11
9	6,8	6,2	8,2	6,2	11
10	6,8	6	8,7	7	11,2
\bar{x}	6,8	6,3	8,26	6,25	11
SD	0,10541	0,34641	0,29136	0,31358	0,52915

NPar Tests

One-Sample Kolmogorov-Smirnov Test

		Kekerasan ODA	Kekerasan ODB	Kekerasan ODC	Kekerasan OGD	Kekerasan OGE
N		10	10	10	10	10
Normal	Mean	6.800	6.300	8.260	6.250	11.000
Parameters ^{a,b}	Std. Deviation	.1054	.3464	.2914	.3136	.5292
Most Extreme	Absolute	.229	.214	.214	.237	.228
Differences	Positive	.171	.214	.214	.237	.228
	Negative	-.229	-.193	-.186	-.213	-.135
Kolmogorov-Smirnov Z		.723	.675	.676	.748	.720
Asymp. Sig. (2-tailed)		.673	.752	.750	.630	.678

a. Test distribution is Normal.

b. Calculated from data.

Test of Homogeneity of Variances

kekerasantablet

Levene Statistic	df1	df2	Sig.
6.648	4	95	.000

Kruskal-Wallis Test

Test Statistics^{a,b}

	kekerasantablet
Chi-Square	42.224
df	4
Asymp. Sig.	.000

a. Kruskal Wallis Test

b. Grouping Variable: sampel

Mann-Whitney Test

ODA-ODB

Test Statistics^b

	kekerasantablet
Mann-Whitney U	85.000
Wilcoxon W	295.000
Z	-3.124
Asymp. Sig. (2-tailed)	.002
Exact Sig. [2*(1-tailed Sig.)]	.001 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODA-ODC

Test Statistics^b

	kekerasantablet
Mann-Whitney U	5.500
Wilcoxon W	215.500
Z	-5.290
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODA-OGD

Test Statistics ^b	
	kekerasantablet
Mann-Whitney U	19.500
Wilcoxon W	229.500
Z	-4.905
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODA-OGE

Test Statistics ^b	
	kekerasantablet
Mann-Whitney U	.000
Wilcoxon W	210.000
Z	-5.433
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-OGC

Test Statistics ^b	
	kekerasantablet
Mann-Whitney U	3.500
Wilcoxon W	213.500
Z	-5.332
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-OGD

Test Statistics ^b	
	kekerasantablet
Mann-Whitney U	193.500
Wilcoxon W	403.500
Z	-.177
Asymp. Sig. (2-tailed)	.860
Exact Sig. [2*(1-tailed Sig.)]	.862 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-OGE

Test Statistics^b

	kekerasantablet
Mann-Whitney U	.000
Wilcoxon W	210.000
Z	-5.420
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

OGC-OGD

Test Statistics^b

	kekerasantablet
Mann-Whitney U	.500
Wilcoxon W	210.500
Z	-5.415
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

OGC-OGE

Test Statistics^b

	kekerasantablet
Mann-Whitney U	3.000
Wilcoxon W	213.000
Z	-5.352
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

OGD-OGE

Test Statistics^b

	kekerasantablet
Mann-Whitney U	.000
Wilcoxon W	210.000
Z	-5.422
Asymp. Sig. (2-tailed)	.000
Exact Sig. [2*(1-tailed Sig.)]	.000 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

Lampiran 5. Hasil pemeriksaan kerapuhan tablet

Obat merk dagang A (ODA)

Bobot tablet	Replikasi		
	1	2	3
Sebelum	2,484	2,664	2,661
Sesudah	2,472	2,652	2,648
Kerapuhan %	0,483	0,450	0,488
$\bar{x} \pm SD$	0,47 \pm 0,02		

Obat merk dagang B (ODB)

Bobot tablet	Replikasi		
	1	2	3
Sebelum	4,003	3,983	3,976
Sesudah	3,981	3,962	3,955
Kerapuhan %	0,549	0,527	0,528
$\bar{x} \pm SD$	0,53 \pm 0,01		

Obat merk dagang C (ODC)

Bobot tablet	Replikasi		
	1	2	3
Sebelum	3,237	3,227	3,246
Sesudah	3,229	3,218	3,238
Kerapuhan %	0,247	0,278	0,246
$\bar{x} \pm SD$	0,23 \pm 0,01		

Obat generik D (OGD)

Bobot tablet	Replikasi		
	1	2	3
Sebelum	4,072	4,002	3,998
Sesudah	4,048	3,979	3,975
Kerapuhan %	0,589	0,574	0,575
$\bar{x} \pm SD$	0,57 \pm 0,008		

Obat Generik E (OGE)

Bobot tablet	Replikasi		
	1	2	3
Sebelum	2,773	2,788	2,762
Sesudah	2,771	2,786	2,76
Kerapuhan %	0,072	0,071	0,072
$\bar{x} \pm SD$	0,07 \pm 0,0003		

Cara perhitungan kerapuhan tablet :

$$\begin{aligned} \% \text{kerapuhan} &= \frac{(\text{bobot awal} - \text{bobot akhir})}{\text{bobot awal}} \times 100\% \\ &= \frac{(2.484 - 2.472)}{2.484} \times 100\% \\ &= \frac{0.012}{2.484} \times 100\% \\ &= 0.483\% \end{aligned}$$

NPar Tests

One-Sample Kolmogorov-Smirnov Test

		%kerapuha n ODA	%kerapuha n ODB	%kerapuha n ODC	%kerapuha n OGD	%kerapuhan OGE
N		3	3	3	3	3
Normal	Mean	.47367	.53467	.25700	.58100	.07167
Parameters ^{a,b}	Std. Deviation	.020648	.012423	.018193	.007211	.000577
Most Extreme	Absolute	.341	.371	.375	.276	.385
Differences	Positive	.244	.371	.375	.276	.282
	Negative	-.341	-.269	-.273	-.203	-.385
Kolmogorov-Smirnov Z		.591	.642	.650	.478	.667
Asymp. Sig. (2-tailed)		.876	.804	.792	.976	.766

Test of Homogeneity of Variances

%kerapuhan

Levene Statistic	df1	df2	Sig.
5.075	4	10	.017

Kruskal-Wallis Test

Test Statistics^{a,b}

	%kerapuhan
Chi-Square	13.524
Df	4
Asymp. Sig.	.009

a. Kruskal Wallis Test

b. Grouping Variable: sampel

Mann-Whitney Test

ODA-ODB

ODA-ODC

Test Statistics^b

	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

Test Statistics^b

	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODA-OGC

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODA-OGE

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.993
Asymp. Sig. (2-tailed)	.046
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-ODC

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-OGD

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODB-OGE

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.993
Asymp. Sig. (2-tailed)	.046
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODC-OGE

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.964
Asymp. Sig. (2-tailed)	.050
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

ODC-OGE

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.993
Asymp. Sig. (2-tailed)	.046
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

OGD-OGE

Test Statistics ^b	
	%kerapuhan
Mann-Whitney U	.000
Wilcoxon W	6.000
Z	-1.993
Asymp. Sig. (2-tailed)	.046
Exact Sig. [2*(1-tailed Sig.)]	.100 ^a

a. Not corrected for ties.

b. Grouping Variable: sampel

Lampiran 6. Hasil pemeriksaan waktu hancur

No	Waktu Hancur				
	ODA	ODB	ODC	OGD	OGE
1	6	209	15	20	120
2	8	210	17	20	122
3	13	218	18	23	130
4	15	220	21	25	132
5	17	223	21	25	135
6	17	226	21	29	138
\bar{x}	12.666	217.666	18.833	23.666	129.5
SD	4.676	6.889	2.562	3.444	7.148
CV	0.369	0.031	0.136	0.145	0.055

One-Sample Kolmogorov-Smirnov Test

		waktu hancur ODA	waktu hancur ODB	waktu hancur ODC	waktu hancur OGD	waktu hancur OGE
N		6	6	6	6	6
Normal	Mean	12.67	217.67	18.83	23.67	129.50
Parameters	Std. Deviation	4.676	6.890	2.563	3.445	7.148
a.,b						
Most	Absolute	.195	.200	.301	.190	.195
Extreme	Positive	.177	.200	.199	.190	.186
Differences	Negative	-.195	-.186	-.301	-.151	-.195
Kolmogorov-Smirnov Z		.478	.491	.738	.465	.477
Asymp. Sig. (2-tailed)		.976	.969	.648	.982	.977

a. Test distribution is Normal.

b. Calculated from data.

Test of Homogeneity of Variances

waktu hancur

Levene Statistic	df1	df2	Sig.
2.249	4	25	.092

ANOVA

waktu hancur

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	197099.133	4	49274.783	1774.176	.000
Within Groups	694.333	25	27.773		
Total	197793.467	29			

Post Hoc Tests

Multiple Comparisons

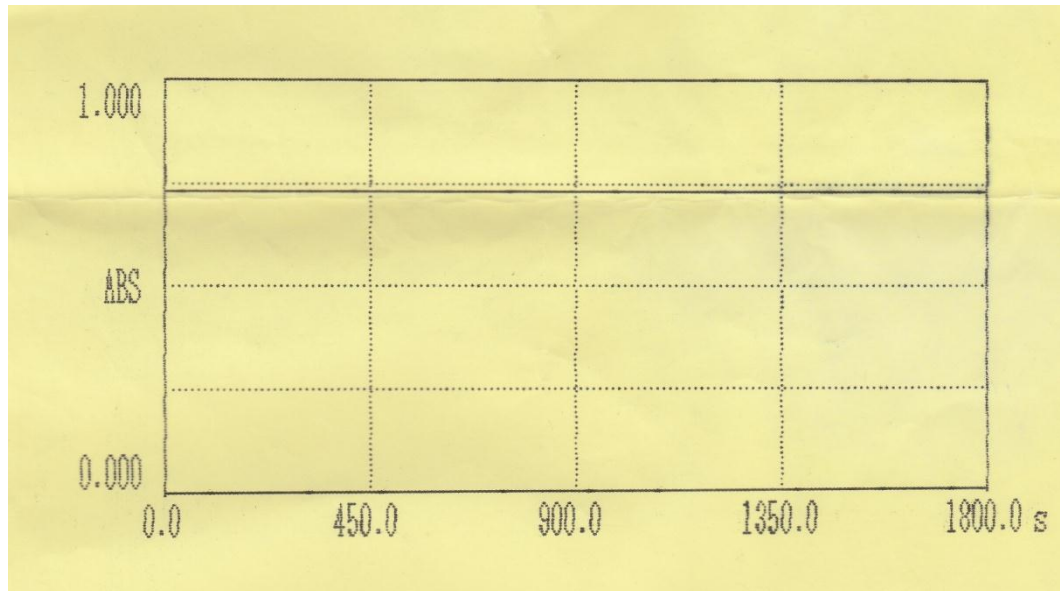
waktu hancur

LSD

(I) sampel	(J) sampel	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
ODA	ODB	-205.000	3.043	.000	-211.27	-198.73
	ODC	-6.167	3.043	.053	-12.43	.10
	OGD	-11.000	3.043	.001	-17.27	-4.73
	OGE	-116.833	3.043	.000	-123.10	-110.57
ODB	ODA	205.000	3.043	.000	198.73	211.27
	ODC	198.833	3.043	.000	192.57	205.10
	OGD	194.000	3.043	.000	187.73	200.27
	OGE	88.167	3.043	.000	81.90	94.43
ODC	ODA	6.167	3.043	.053	-.10	12.43
	ODB	-198.833	3.043	.000	-205.10	-192.57
	OGD	-4.833	3.043	.125	-11.10	1.43
	OGE	-110.667	3.043	.000	-116.93	-104.40
OGD	ODA	11.000	3.043	.001	4.73	17.27
	ODB	-194.000	3.043	.000	-200.27	-187.73
	ODC	4.833	3.043	.125	-1.43	11.10
	OGE	-105.833	3.043	.000	-112.10	-99.57
OGE	ODA	116.833	3.043	.000	110.57	123.10
	ODB	-88.167	3.043	.000	-94.43	-81.90
	ODC	110.667	3.043	.000	104.40	116.93
	OGD	105.833	3.043	.000	99.57	112.10

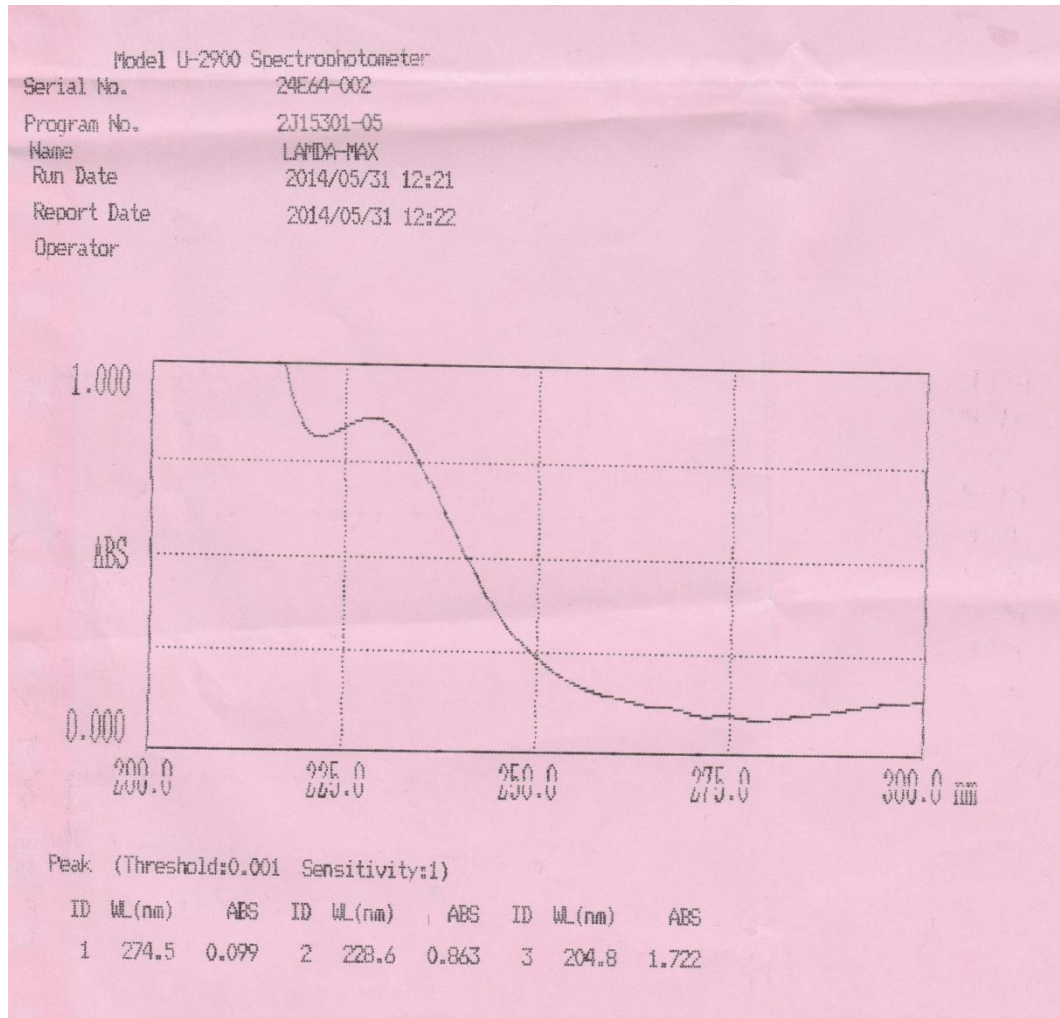
*. The mean difference is significant at the 0.05 level.

Lampiran 7. Penentuan *operating time* glibenklamid



Data List (List Interval(s):60.0)

ID	TIME(s)	ABS	ID	TIME(s)	ABS	ID	TIME(s)	ABS
1	0.0	0.732	2	60.0	0.732	3	120.0	0.732
4	180.0	0.732	5	240.0	0.731	6	300.0	0.732
7	360.0	0.732	8	420.0	0.731	9	480.0	0.732
10	540.0	0.732	11	600.0	0.732	12	660.0	0.732
14	780.0	0.733	15	840.0	0.732	16	900.0	0.732
19	1080.0	0.733	20	1140.0	0.733	21	1200.0	0.733
22	1260.0	0.733	23	1320.0	0.733	24	1380.0	0.734
25	1440.0	0.734	26	1500.0	0.734	27	1560.0	0.734
28	1620.0	0.734	29	1680.0	0.735	30	1740.0	0.735
31	1800.0	0.735						

Lampiran 8. Penentuan panjang gelombang maksimum glibenklamid

Lampiran 9. Penentuan kurva baku glibenklamid

- a. Cara pembuatan seri konsentrasi glibenklamid

Pembuatan larutan baku 200 ppm sebanyak 50 mL

Penimbangan glibenklamid $200\text{mg}/1000\text{mL} \times 50 \text{ mL} = 10\text{mg}$

Pengenceran larutan baku menjadi 20ppm

$$\begin{aligned} V_1 \cdot C_1 &= V_2 \cdot C_2 \\ V_1 \cdot 200\text{ppm} &= 25\text{mL} \cdot 20\text{ppm} \\ V_1 &= 2.5 \text{ mL ad } 10 \text{ mL} \end{aligned}$$

Perhitungan seri konsentrasi

- a. Konsentrasi 1mg/L sebanyak 10 mL

$$\begin{aligned} V_1 \cdot C_1 &= V_2 \cdot C_2 \\ V_1 \cdot 20\text{ppm} &= 10\text{mL} \cdot 1\text{ppm} \\ V_1 &= 0.5 \text{ mL ad } 10 \text{ mL} \end{aligned}$$

- b. Konsentrasi 2 mg/L sebanyak 10 mL

$$\begin{aligned} V_1 \cdot C_1 &= V_2 \cdot C_2 \\ V_1 \cdot 20\text{ppm} &= 10\text{mL} \cdot 2\text{ppm} \\ V_1 &= 1 \text{ mL ad } 10 \text{ mL} \end{aligned}$$

- c. Konsentrasi 4 mg/L sebanyak 10 mL

$$\begin{aligned} V_1 \cdot C_1 &= V_2 \cdot C_2 \\ V_1 \cdot 20\text{ppm} &= 10\text{mL} \cdot 4\text{ppm} \\ V_1 &= 2 \text{ mL ad } 10 \text{ mL} \end{aligned}$$

d. Konsentrasi 6 mg/L sebanyak 10 mL

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$V_1 \cdot 20\text{ppm} = 10\text{mL} \cdot 6\text{ppm}$$

$$V_1 = 3 \text{ mL ad } 10 \text{ mL}$$

e. Konsentrasi 8 mg/L sebanyak 10 mL

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$V_1 \cdot 20\text{ppm} = 10\text{mL} \cdot 8\text{ppm}$$

$$V_1 = 4 \text{ mL ad } 10 \text{ mL}$$

b. Kurva baku glibenklamid

PPM	A
1	0.062
2	0.136
4	0.286
6	0.415
8	0.542

Regresi linier

$$a = -0,0001$$

$$b = 0,068$$

$$r = 0,999$$

$$y = 0,068 x - 0,0001$$

Lampiran 10. Hasil pemeriksaan keseragaman kadar

No	Kadar Glibenklamid Dalam Tablet (mg)				
	ODA	ODB	ODC	OGD	OGE
1	4,794	5,188	4,838	4,794	5,042
2	4,488	4,459	4,867	4,867	5,290
3	4,750	5,173	5,129	4,779	4,925
4	4,590	4,707	4,707	4,750	4,983
5	4,707	4,677	4,852	4,736	5,144
6	4,459	5,086	4,867	4,415	4,765
7	4,371	4,386	4,765	4,677	4,707
8	4,459	4,677	5,115	4,707	4,736
9	4,400	4,765	4,692	4,896	4,663
10	4,736	4,546	4,852	4,663	4,357
\bar{x}	4,575	4,766	4,868	4,728	4,861
SD	0,159	0,289	0,148	0,133	0,270
CV(%)	0,034	0,061	0,030	0,028	0,055

Contoh perhitungan keseragaman kadar tablet glibenklamid

Persamaan kurva baku $Y = 0.0686x - 0.0001$

Obat merk dagang A (ODA)

No	BOBOT		Absorbansi	Kadar mg/L	Kadar mg/ml	Kadar /Tablet (mg)	Kadar % dalam tablet
	Tablet (mg)	Sampel (mg)					
1	124	62	0,329	4,794	0,0048	4,794	95,889
2	123	61,5	0,308	4,488	0,0045	4,488	89,767
3	125	62,5	0,326	4,751	0,0048	4,750	95,015
4	124	62	0,315	4,59	0,0046	4,590	91,808
5	124	62	0,323	4,707	0,0047	4,707	94,140
6	123	61,5	0,306	4,459	0,0045	4,459	89,184
7	124	62	0,300	4,372	0,0044	4,371	87,434
8	125	62,5	0,306	4,459	0,0045	4,459	89,184
9	125	62,5	0,302	4,401	0,0044	4,400	88,017
10	123	61,5	0,325	4,736	0,0047	4,736	94,723

$$Y = 0.0686x - 0.0001$$

$$\begin{aligned} \text{Konsentrasi} &= \frac{\text{Absorbansi} - 0.0001}{0.0686} \\ &= \frac{0.329 - 0.0001}{0.0686} \\ &= 4.794 \text{ mg/L} \\ &= 0.005 \text{ mg/ml} \end{aligned}$$

Lampiran 11. Hasil pemeriksaan % kadar terdisolusi

a. Produk bermerk dagang A (ODA)

Waktu (menit)	Kadar Obat Terdisolusi						$\bar{x} \pm SD$
	Replikasi						
	1	2	3	4	5	6	
5	67,4316	66,9372	68,5846	67,4864	67,4864	68,0355	67,66±0,57
15	72,8104	74,8195	72,6413	72,08	73,1783	72,0861	72,93±1,01
30	83,4487	76,7408	75,6365	83,3058	77,2777	76,1734	78,76±3,61
45	86,0948	79,2234	77,5578	86,4107	79,7664	77,5517	81,10±4,08
60	88,7601	87,2155	82,786	88,991	86,6664	84,9763	86,56±2,36

b. Produk bermerk dagang B (ODB)

Waktu (menit)	Kadar Obat Terdisolusi						$\bar{x} \pm SD$
	Replikasi						
	1	2	3	4	5	6	
5	71,3302	71,3302	68,0355	71,8793	71,3302	67,4864	70,23±1,93
15	79,2612	79,2612	74,2826	77,62	79,2612	73,7274	77,23±2,58
30	81,2313	81,7805	75,6487	81,2191	81,7805	78,382	80,00±2,48
45	90,3522	84,8671	77,57	88,6926	84,8671	79,7847	84,35±4,94
60	92,426	89,0764	80,0526	89,6499	89,0764	82,8409	87,18±4,69

c. Produk bermerk dagang C (ODC)

Waktu (menit)	Kadar Obat Terdisolusi						$\bar{x} \pm SD$
	Replikasi						
	1	2	3	4	5	6	
5	70,7811	66,9372	71,3302	70,2319	68,5846	72,4284	70,04±1,98
15	77,6078	73,1722	84,7524	76,5035	72,0922	80,3717	77,41±4,685
30	79,5596	78,3698	86,2344	78,4431	78,3759	82,9031	80,64±3,24
45	82,0727	82,5181	88,2716	80,944	81,9751	84,9037	83,44±2,70
60	90,0953	88,8994	92,5175	87,307	87,8012	91,3095	89,65±2,03

d. Produk generik D (OGD)

Waktu (menit)	Kadar Obat Terdisolusi						$\bar{x} \pm SD$
	Replikasi						
	1	2	3	4	5	6	
5	65,839	62,5443	65,2899	66,9372	63,6425	64,7408	64,83±1,56
15	68,767	65,4357	70,9574	74,2704	64,8988	72,0495	69,39±3,72
30	76,6615	67,8024	74,4833	76,7347	67,2594	74,4894	72,91±4,28
45	79,1441	69,0892	78,5889	79,7664	80,0715	79,6932	77,72±4,26
60	85,4888	80,8152	86,0257	86,6664	84,7811	85,4949	84,87±2,08

e. Produk generik E (OGE)

Waktu (menit)	Kadar Obat Terdisolusi						$\bar{x} \pm SD$
	Replikasi						
	1	2	3	4	5	6	
5	58,7005	63,6425	71,8793	60,3479	64,7408	71,8793	65,19±5,61
15	68,1386	72,5864	75,9726	66,5095	73,6969	75,9726	72,14±3,99
30	69,4376	74,4833	80,6517	70,5358	75,606	80,6517	75,22±4,79
45	72,39	75,8433	83,177	73,5004	76,9781	83,177	77,51±4,68
60	85,2509	85,4461	87,368	85,2753	84,9458	87,368	85,94±1,11

Waktu	abs	Kadar	Terdisolusi	Koreksi	Total Koreksi	Total Terdisolusi	% Terdisolusi	Perbandingan
0	0	0	0		0	0	0	0
5	0,125	1,697	1,528	0	0	1,528	30,551	67,431
15	0,133	1,814	1,632	0,016	0,017	1,649	32,988	72,810
30	0,15	2,061	1,855	0,018	0,035	1,890	37,808	83,448
45	0,153	2,105	1,895	0,020	0,055	1,950	39,007	86,094
60	0,156	2,149	1,934	0,021	0,076	2,011	40,215	88,760

$$Y = 0.0686x - 0.0001$$

$$\text{Konsentrasi} = \frac{\text{Absorbansi} - 0.0001}{0.0686}$$

$$= \frac{0.125 - 0.0001}{0.0686}$$

$$= 1.697 \text{ mg/L}$$

$$\begin{aligned}
 \% \text{ terdissolusi} &= \frac{(\text{kadar} \times \text{media}) + \text{total koreksi}}{\text{dosis}} \times 100 \% \\
 &= \frac{(1.697 \times 0.9) + 0}{5\text{mg}} \times 100 \% \\
 &= \frac{1.528}{5\text{mg}} \times 100 \% \\
 &= 30.551\% \\
 \text{Perbandingan} &= \frac{30.551\%}{45.308\%} \times 100 \% \\
 &= 67.431\%
 \end{aligned}$$

Perbandingan adalah untuk mengatasi glibenklamid yang praktis sukar larut dalam air sehingga kadar terdissolusi ditetapkan dengan model pendekatan pada 45.308% saja. Dengan cara yaitu 1 tablet glibenklamid dihaluskan atau digerus kemudian di larutkan dalam media disolusi 900ml Hcl 0.1 N dan diputar selama 60 menit dengan metode dayung 50 Rpm. Kemudian didapat absorbansi 0.164 dan dihitung kadarnya yaitu 45.308 yang dianggap 100%.

Lampiran 12. Hasil perhitungan Q₄₅

Replikasi	Q ₄₅ (%)				
	ODA	ODB	ODC	OGD	OGE
1	86,095	90,352	82,073	79,144	72,39
2	79,223	84,867	82,518	69,089	75,843
3	77,558	77,57	88,272	78,589	83,177
4	86,411	88,693	80,944	79,766	73,5
5	79,766	84,867	81,975	80,071	76,978
6	77,552	79,785	84,904	79,693	83,177
\bar{x}	81,101	84,356	83,448	77,726	77,511
SD	4,0888	4,9443	2,7049	4,2634	4,6815

NPar Tests

One-Sample Kolmogorov-Smirnov Test

		Q45ODA	Q45ODB	Q45ODC	Q45OGD	Q45OGE
N		6	6	6	6	6
Normal Parameters ^{a,b}	Mean	81.10083	84.35567	83.44767	77.72533	77.51083
	Std. Deviation	4.088851	4.944242	2.705039	4.263402	4.681585
Most Extreme Differences	Absolute	.295	.208	.301	.414	.220
	Positive	.295	.156	.301	.291	.212
	Negative	-.222	-.208	-.177	-.414	-.220
Kolmogorov-Smirnov Z		.722	.509	.738	1.013	.540
Asymp. Sig. (2-tailed)		.675	.958	.648	.256	.933

a. Test distribution is Normal.

b. Calculated from data.

Test of Homogeneity of Variances

Q45

Levene Statistic	df1	df2	Sig.
.620	4	25	.652

ANOVA

Q45

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	240.070	4	60.017	3.388	.024
Within Groups	442.876	25	17.715		
Total	682.946	29			

Post Hoc Tests

Multiple Comparisons

Q45

LSD

(I) SAMPE L	(J) SAMPE L	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
ODA	ODB	-3.25483	2.43002	.192	-8.2596	1.7499
	ODC	-2.34683	2.43002	.343	-7.3516	2.6579
	OGD	3.37550	2.43002	.177	-1.6292	8.3802
	OGE	3.59000	2.43002	.152	-1.4147	8.5947
ODB	ODA	3.25483	2.43002	.192	-1.7499	8.2596
	ODC	.90800	2.43002	.712	-4.0967	5.9127
	OGD	6.63033	2.43002	.011	1.6256	11.6351
	OGE	6.84483	2.43002	.009	1.8401	11.8496
ODC	ODA	2.34683	2.43002	.343	-2.6579	7.3516
	ODB	-.90800	2.43002	.712	-5.9127	4.0967
	OGD	5.72233	2.43002	.027	.7176	10.7271
	OGE	5.93683	2.43002	.022	.9321	10.9416
OGD	ODA	-3.37550	2.43002	.177	-8.3802	1.6292
	ODB	-6.63033	2.43002	.011	-11.6351	-1.6256
	ODC	-5.72233	2.43002	.027	-10.7271	-.7176
	OGE	.21450	2.43002	.930	-4.7902	5.2192
OGE	ODA	-3.59000	2.43002	.152	-8.5947	1.4147
	ODB	-6.84483	2.43002	.009	-11.8496	-1.8401
	ODC	-5.93683	2.43002	.022	-10.9416	-.9321
	OGD	-.21450	2.43002	.930	-5.2192	4.7902

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

Lampiran 13. Hasil perhitungan DE₆₀

Replikasi	DE60(%)				
	ODA	ODB	ODC	OGD	OGE
1	77,079	79,878	76,686	72,194	67,646
2	73,848	78,225	74,946	65,775	71,34
3	72,353	72,291	81,764	71,965	76,691
4	77,005	78,84	75,477	73,799	68,068
5	73,776	78,225	74,655	68,906	72,21
6	72,576	73,692	79,163	72,335	76,691
\bar{x}	74,439	76,859	77,115	70,829	72,108
SD	2,1055	3,0876	2,8083	2,9489	3,9707

NPar Tests

One-Sample Kolmogorov-Smirnov Test

		DEODA	DEODB	DEODC	DEOGD	DEOGE
N		6	6	6	6	6
Normal Parameters ^{a,b}	Mean	74.43940	76.85850	77.11517	70.82900	72.10767
	Std. Deviation	2.105510	3.087625	2.808229	2.949017	3.970870
	Most Extreme Differences	Absolute	.277	.338	.227	.317
	Positive	.277	.181	.227	.157	.179
	Negative	-.222	-.338	-.190	-.317	-.209
Kolmogorov-Smirnov Z		.679	.827	.557	.776	.512
Asymp. Sig. (2-tailed)		.745	.501	.916	.584	.956

a. Test distribution is Normal.

b. Calculated from data.

Test of Homogeneity of Variances

DE60

Levene Statistic	df1	df2	Sig.
.682	4	25	.611

ANOVA

DE60

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	188.041	4	47.010	5.075	.004
Within Groups	231.585	25	9.263		
Total	419.627	29			

Multiple Comparisons

DE60

Tukey HSD

(I) SAMPE L	(J) SAMPE L	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
ODA	ODB	-2.419000	1.757215	.648	-7.57972	2.74172
	ODC	-2.675667	1.757215	.558	-7.83638	2.48505
	OGD	3.610500	1.757215	.271	-1.55022	8.77122
	OGE	2.331833	1.757215	.678	-2.82888	7.49255
ODB	ODA	2.419000	1.757215	.648	-2.74172	7.57972
	ODC	-.256667	1.757215	1.000	-5.41738	4.90405
	OGD	6.029500	1.757215	.016	.86878	11.19022
	OGE	4.750833	1.757215	.082	-.40988	9.91155
ODC	ODA	2.675667	1.757215	.558	-2.48505	7.83638
	ODB	.256667	1.757215	1.000	-4.90405	5.41738
	OGD	6.286167	1.757215	.012	1.12545	11.44688
	OGE	5.007500	1.757215	.060	-.15322	10.16822
OGD	ODA	-3.610500	1.757215	.271	-8.77122	1.55022
	ODB	-6.029500	1.757215	.016	-11.19022	-.86878
	ODC	-6.286167	1.757215	.012	-11.44688	-1.12545
	OGE	-1.278667	1.757215	.948	-6.43938	3.88205
OGE	ODA	-2.331833	1.757215	.678	-7.49255	2.82888
	ODB	-4.750833	1.757215	.082	-9.91155	.40988
	ODC	-5.007500	1.757215	.060	-10.16822	.15322
	OGD	1.278667	1.757215	.948	-3.88205	6.43938

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

Lampiran 14. Hasil perhitungan nilai F2 dan F1

Produk uji :

1. Obat merk dagang A (ODA)
2. Obat merk dagang B (ODB)
3. Obat merk dagang C (ODC)
4. Obat generik D (OGD)
5. Obat Generik E (OGE)

No	Produk Obat	similarity factor	
		F1	F2
1	ODA -ODB	3,098	76,732
2	ODA-ODC	3,098	76,732
3	ODA-OGD	4,467	70,731
4	ODA-OGE	2,842	78,134
5	ODB-ODC	0,551	90,146
6	ODB-OGD	7,338	60,205
7	ODB-OGE	5,762	64,838
8	ODC-OGD	7,846	59,314
9	ODC-OGE	6,278	64,239
10	OGD-ODE	1,7	85,354

Contoh perhitungan F1 dan F2

Waktu (menit)	R	T	R-T	(R-T)2
5	67,66	70,232	2,572	6,6135
15	72,936	77,236	4,3	18,487
30	78,764	80,007	1,243	1,5456
45	81,101	84,356	3,255	10,594
60	86,566	87,187	0,621	0,3858
			Σ	37,626

$$\begin{aligned}
F_2 &= 50 \log \left[\frac{100}{\sqrt{\frac{1 + \sum_{t=1}^n (R_t - T_t)^2}{n}}} \right] \\
&= 50 \log \left[\frac{100}{\sqrt{1 + \frac{37.626}{5}}} \right] \\
&= 50 \log \left[\frac{100}{\sqrt{1 + 7.5252}} \right] \\
&= 50 \log \left[\frac{100}{\sqrt{8.5252}} \right] \\
&= 50 \log \left[\frac{100}{2.9198} \right] \\
&= 50 \log [34.24892] \\
&= 50.1.5346 \\
&= 76.732
\end{aligned}$$

Waktu (menit)	R	T	R-T
5	67,66	70,232	2,572
15	72,936	77,236	4,3
30	78,764	80,007	1,243
45	81,101	84,356	3,255
60	86,566	87,187	0,621
	$\Sigma = 387,027$		$\Sigma = 11,991$

$$\begin{aligned}
F_1 &= \left\{ \left[\sum_{t=1}^n |R_t - T_t| \right] / \left[\sum_{t=1}^n R_t \right] \right\} \times 100 \\
&= \frac{11.991}{387.027} \times 100 \\
&= 3.098
\end{aligned}$$

Lampiran 15. Foto alat



Dissolution tester tipe 2



Spektrofotometer UV Vis



Disintegration tester



Friabilator tester



Hardness tester



Neraca analitik