

LAMPIRAN A
HASIL UJI MUTU FISIK GRANUL

Mutu fisik yang diuji	Replikasi	Formula Tablet Sublingual Propranolol Hidroklorida				Persyaratan
		F I	F II	F III	F IV	
Waktu alir (detik)	I	9.57	8.54	7.56	6.01	Tidak lebih dari 10 detik (Banker & Anderson, 1994)
	II	9.45	8.65	7.41	6.05	
	III	9.37	8.45	7.49	6.02	
	\bar{X}	9.46	8.55	7.49	6.03	
	SD	0.10	0.10	0.08	0.02	
Sudut diam (derajat)	I	27.32	25.01	26.56	26.56	25-40 Baik (Wells, 1993)
	II	27.12	25.10	26.56	26.67	
	III	27.3	25.07	26.56	25.65	
	\bar{X}	27.25	25.06	26.56	26.29	
	SD	0.34	0.33	0.34	0.34	
Indeks kompresibilitas (persen)	I	19.00	22.00	12.99	12.00	12 -16% baik; 18-23% cukup dapat mengalir (Wells, 1993)
	II	19.05	22.00	13.00	12.10	
	III	19.00	22.10	13.00	12.11	
	\bar{X}	19.02	22.03	13.00	12.07	
	SD	0.03	0.06	0.01	0.06	

LAMPIRAN B

HASIL UJI KEKERASAN TABLET SUBLINGUAL
PROPRANOLOL HIDROKLORIDA

BATCH I

No	Kekerasan Tablet Sublingual Propranolol Hidroklorida (kp)			
	Formula I	Formula II	Formula III	Formula IV
1	5,9	7,3	4,4	7,1
2	6,4	7,3	4,6	7,2
3	6,3	7,4	5,6	6,9
4	7,1	7,2	5,6	5,4
5	6,4	6,9	4,8	6,7
6	7,1	6,2	4,1	6,5
7	5,8	7,4	5,8	5,2
8	7,3	7,1	4,2	6,7
9	7,1	6,1	4,8	6,2
10	6,8	6,0	4,4	6,4
$\bar{X} \pm SD$	6,62 ± 0,53	6,89 ± 0,57	4,83 ± 0,62	6,43 ± 0,67
SD rel (%)	8,08	8,22	12,88	10,42

BATCH II

No	Kekerasan Tablet Sublingual Propranolol Hidroklorida (kp)			
	Formula I	Formula II	Formula III	Formula IV
1	6,8	7,4	5,8	6,4
2	7,3	7,5	5,4	7,3
3	7,1	6,9	4,8	7,1
4	6,3	6,6	4,1	6,5
5	5,6	6,7	5,6	5,3
6	5,8	6,9	4,8	6,5
7	7,1	7,1	4,7	6,2
8	7,1	7,6	5,2	5,6
9	6,3	7,4	4,4	6,5
10	5,5	6,4	5,4	6,1
$\bar{X} \pm SD$	6,49 ± 0,68	7,05 ± 0,41	5,02 ± 0,55	6,35 ± 0,60
SD rel (%)	10,51	5,88	10,90	9,51

BATCH III

No	Kekerasan Tablet Sublingual Propranolol Hidroklorida (kp)			
	Formula I	Formula II	Formula III	Formula IV
1	6.5	7.2	4.6	6.5
2	7,2	7.1	4.6	7.6
3	6.9	6.9	4.7	6.5
4	5.6	7.3	5.6	6.8
5	5.8	6.9	4,5	7.1
6	5.7	6.9	4.8	7.2
7	7.1	7.3	5.2	6.9
8	6.6	7.3	4.9	5.4
9	5.5	7.4	5	6.7
10	5.9	6.7	4.9	6.5
$\bar{X} \pm SD$	6,18 \pm 0,60	7,10 \pm 0,24	4,92 \pm 0,32	6,72 \pm 0,58
SD rel (%)	9,73	3,32	6,49	8,70

LAMPIRAN C
HASIL UJI KERAPUHAN TABLET SUBLINGUAL
PROPRANOLOL HIDROKLORIDA

Formula	Replikasi	Berat awal (gram)	Berat akhir (gram)	Kerapuhan (%)	$\bar{X} \pm SD$	SDrel (%)
I	1	7010	6990	0.2853	0.2850	0.11
	2	7025	7005	0.2847	±	
	3	7015	6995	0.2851	0.0003	
II	1	7037	7030	0.0995	0.0807	20.20
	2	7020	7015	0.0712	±	
	3	7015	7010	0.0713	0.0163	
III	1	7020	6980	0.5698	0.5605	4.16
	2	7010	6969.5	0.5777	±	
	3	7023	6985.5	0.5340	0.0233	
IV	1	7050	7040	0.1418	0.1511	5.28
	2	7069	7058	0.1556	±	
	3	7065	7054	0.1557	0.0080	

LAMPIRAN D
HASIL UJI WAKTU HANCUR TABLET SUBLINGUAL
PROPRANOLOL HIDROKLORIDA

Replikasi	Waktu Hancur (menit)			
	Formula I	Formula II	Formula III	Formula IV
1	1,55	4,10	1,00	2,30
2	1,45	4,00	1,30	2,45
3	1,50	4,20	1,30	2,50
$\bar{X} \pm SD$	1,5 \pm 0,05	4,1 \pm 0,1	1,35 \pm 0,09	2,42 \pm 0,10
SD Rel(%)	3,33	2,44	6,42	4,31

LAMPIRAN E

HASIL UJI KESERAGAMAN KANDUNGAN TABLET
SUBLINGUAL PROPRANOLOL HIDROKLORIDA

Hasil Uji Keseragaman Kandungan Tablet Formula I *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.543	16.23	355	16.46	98.59
1.514	16.23	355	16.46	98.59
1.415	16.18	354	16.37	98.87
1.513	16.00	350	16.00	100.00
1.517	16.46	360	16.93	97.22
1.511	16.18	354	16.37	98.87
1.499	16.05	351	16.09	99.72
1.521	16.00	350	16.00	100.00
1.537	16.46	360	16.93	97.22
1.513	16.00	350	16.00	100.00
			\bar{X}	98.91
			SD	1.06
			KV	1.07

Hasil Uji Keseragaman Kandungan Tablet Formula I *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.513	16.50	361.0	17.02	96.95
1.517	16.46	360.0	16.93	97.22
1.511	16.23	355.0	16.46	98.59
1.499	16.46	360.0	16.93	97.22
1.532	16.46	360.0	16.93	97.22
1.513	16.00	350.0	16.00	100.00
1.542	15.54	340.0	15.10	102.94
1.572	16.23	355.0	16.46	98.59
1.523	16.46	360.0	16.93	97.22
1.521	16.46	360.0	16.93	97.22
			\bar{X}	98.32
			SD	1.89
			KV	1.92

Hasil Uji Keseragaman Kandungan Tablet Formula I *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.521	16.00	350	16.00	100.00
1.484	16.46	360	16.93	97.22
1.476	16.23	355	16.46	98.59
1.511	16.00	350	16.00	100.00
1.495	16.18	354	16.37	98.87
1.532	16.46	360	16.93	97.22
1.487	16.00	350	16.00	100.00
1.513	16.46	360	16.93	97.22
1.564	16.91	370	17.88	94.59
1.523	16.00	350	16.00	100.00
			\bar{X}	98.37
			SD	1.80
			KV	1.83

Hasil Uji Keseragaman Kandungan Tablet Formula II *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.511	16.46	360	16.93	97.22
1.499	16.09	352	16.18	99.43
1.521	16.23	355	16.46	98.59
1.537	16.46	360	16.93	97.22
1.532	16.14	353	16.28	99.15
1.513	16.09	352	16.18	99.43
1.542	16.27	356	16.55	98.31
1.572	16.37	358	16.74	97.77
1.532	16.09	352	16.18	99.43
1.513	16.05	351	16.09	99.72
			\bar{X}	98.63
			SD	0.95
			KV	0.97

Hasil Uji Keseragaman Kandungan Tablet Formula II *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.484	16.23	355	16.46	98.59
1.476	16.32	357	16.65	98.04
1.511	16.27	356	16.55	98.31
1.495	15.95	349	15.91	100.29
1.532	15.77	345	15.55	101.45
1.487	16.82	368	17.69	95.11
1.513	16.78	367	17.59	95.37
1.551	16.55	362	17.12	96.69
1.523	16.69	365	17.40	95.89
1.432	16.23	355	16.46	98.59
			\bar{X}	97.83
			SD	2.08
			KV	2.13

Hasil Uji Keseragaman Kandungan Tablet Formula II *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.543	16.32	357	16.65	98.04
1.574	16.23	355	16.46	98.59
1.499	16.46	360	16.93	97.22
1.587	16.69	365	17.40	95.89
1.523	16.73	366	17.50	95.63
1.601	15.77	345	15.55	101.45
1.532	16.00	350	16.00	100.00
1.526	16.00	350	16.00	100.00
1.519	16.46	360	16.93	97.22
1.521	16.46	360	16.93	97.22
			\bar{X}	98.13
			SD	1.88
			KV	1.92

Hasil Uji Keseragaman Kandungan Tablet Formula III *Batch I*

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.511	16.00	350	16.00	100.00
1.495	16.46	360	16.93	97.22
1.532	16.46	360	16.93	97.22
1.487	16.69	365	17.40	95.89
1.513	16.00	350	16.00	100.00
1.532	16.46	360	16.93	97.22
1.513	16.46	360	16.93	97.22
1.542	16.00	350	16.00	100.00
1.572	16.46	360	16.93	97.22
1.532	16.00	350	16.00	100.00
\bar{X}				98.20
SD				1.60
KV				1.63

Hasil Uji Keseragaman Kandungan Tablet Formula III *Batch II*

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.415	16.00	350	16.00	100.00
1.513	16.46	360	16.93	97.22
1.517	16.23	355	16.46	98.59
1.511	15.54	340	15.10	102.94
1.532	16.46	360	16.93	97.22
1.487	16.00	350	16.00	100.00
1.513	16.46	360	16.93	97.22
1.532	16.91	370	17.88	94.59
1.513	16.46	360	16.93	97.22
1.551	16.00	350	16.00	100.00
\bar{X}				98.50
SD				2.32
KV				2.35

Hasil Uji Keseragaman Kandungan Tablet Formula III *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.523	16.00	350.0	16.00	100.00
1.601	16.46	360.0	16.93	97.22
1.532	16.46	360.0	16.93	97.22
1.526	16.46	360.0	16.93	97.22
1.519	16.00	350.0	16.00	100.00
1.532	16.23	355.0	16.46	98.59
1.487	16.00	350.0	16.00	100.00
1.513	16.46	360.0	16.93	97.22
1.551	16.46	360.0	16.93	97.22
1.523	16.23	355.0	16.46	98.59
\bar{X}				98.33
SD				1.28
KV				1.30

Hasil Uji Keseragaman Kandungan Tablet Formula IV *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.513	16.00	350.0	16.00	100.00
1.532	15.54	340.0	15.10	102.94
1.513	15.77	345.0	15.55	101.45
1.542	16.00	350.0	16.00	100.00
1.572	16.46	360.0	16.93	97.22
1.511	16.46	360.0	16.93	97.22
1.532	16.46	360.0	16.93	97.22
1.487	16.46	360.0	16.93	97.22
1.513	15.54	340.0	15.10	102.94
1.532	15.77	345.0	15.55	101.45
\bar{X}				99.77
SD				2.40
KV				2.41

Hasil Uji Keseragaman Kandungan Tablet Formula IV *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.513	16.00	350.0	16.00	100.00
1.542	16.46	360.0	16.93	97.22
1.572	16.69	365.0	17.40	95.89
1.511	16.23	355.0	16.46	98.59
1.532	16.46	360.0	16.93	97.22
1.513	16.00	350.0	16.00	100.00
1.532	16.46	360.0	16.93	97.22
1.513	16.00	350.0	16.00	100.00
1.542	16.91	370.0	17.88	94.59
1.572	16.00	350.0	16.00	100.00
			\bar{x}	98.07
			SD	1.95
			KV	1.99

Hasil Uji Keseragaman Kandungan Tablet Formula IV *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
1.511	16.46	360.0	16.93	97.22
1.532	16.00	350.0	16.00	100.00
1.513	16.23	355.0	16.46	98.59
1.532	16.46	360.0	16.93	97.22
1.513	16.46	360.0	16.93	97.22
1.526	16.00	350.0	16.00	100.00
1.519	16.46	360.0	16.93	97.22
1.532	16.00	350.0	16.00	100.00
1.487	16.46	360.0	16.93	97.22
1.513	16.46	360.0	16.93	97.22
			\bar{x}	98.19
			SD	1.32
			KV	1.34

LAMPIRAN F
HASIL PENETAPAN KADAR TABLET SUBLINGUAL
PROPRANOLOL HIDROKLORIDA

Batch I

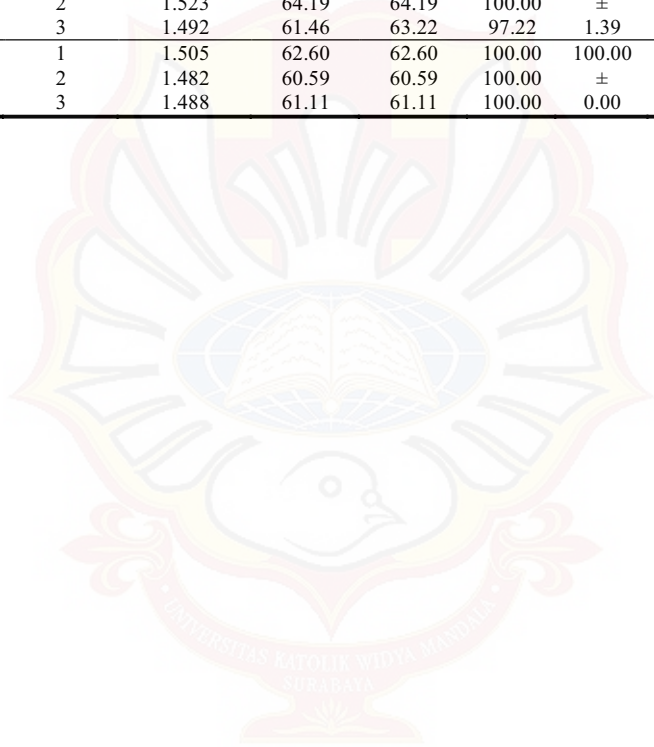
Formula	Replikasi	Absorbansi	Csampel ($\mu\text{g/ml}$)	Cteoritis ($\mu\text{g/ml}$)	Kadar (%)	$\bar{X} \pm \text{SD}$	SDrel(%)
I	1	1.532	64.98	66.84	97.22	98.15	1.63
	2	1.342	48.30	49.68	97.22	\pm	
	3	1.435	56.46	56.46	100.00	1.60	
II	1	1.412	54.44	54.44	100.00	98.15	1.63
	2	1.524	64.27	66.11	97.22	\pm	
	3	1.499	62.08	63.85	97.22	1.60	
III	1	1.492	61.46	61.46	100.00	100.00	0.00
	2	1.512	63.22	63.22	100.00	\pm	
	3	1.501	62.25	62.25	100.00	0.00	
IV	1	1.517	63.66	63.66	100.00	99.07	1.62
	2	1.511	63.13	63.13	100.00	\pm	
	3	1.522	64.09	65.92	97.22	1.60	

Batch II

Formula	Replikasi	Absorbansi	Csampel ($\mu\text{g/ml}$)	Cteoritis ($\mu\text{g/ml}$)	Kadar (%)	$\bar{X} \pm \text{SD}$	SDrel(%)
I	1	1.423	55.41	55.41	100.00	98.63	2.41
	2	1.432	56.2	58.61	95.89	\pm	
	3	1.512	63.22	63.22	100.00	2.37	
II	1	1.473	59.80	61.51	97.22	97.22	0.00
	2	1.413	54.53	56.09	97.22	\pm	
	3	1.339	48.03	49.40	97.22	0.00	
III	1	1.465	59.09	59.09	100.00	99.53	0.82
	2	1.410	54.27	54.27	100.00	\pm	
	3	1.427	55.76	56.56	98.59	0.81	
IV	1	1.510	63.05	64.85	97.22	97.68	0.81
	2	1.388	52.33	53.08	98.59	\pm	
	3	1.391	52.60	54.10	97.22	0.79	

Batch III

Formula	Replikasi	Absorbansi	Csampil ($\mu\text{g/ml}$)	Cteoritis ($\mu\text{g/ml}$)	Kadar (%)	$\bar{X} \pm \text{SD}$	SDrel(%)
I	1	1.511	63.13	65.84	95.89	96.33	0.80
	2	1.481	60.50	62.23	97.22	\pm	
	3	1.423	55.41	57.78	95.89	0.77	
II	1	1.324	46.72	46.72	100.00	100.48	0.83
	2	1.412	54.44	54.44	100.00	\pm	
	3	1.332	47.42	46.74	101.45	0.84	
III	1	1.519	63.83	64.74	98.59	98.60	1.41
	2	1.523	64.19	64.19	100.00	\pm	
	3	1.492	61.46	63.22	97.22	1.39	
IV	1	1.505	62.60	62.60	100.00	100.00	0.00
	2	1.482	60.59	60.59	100.00	\pm	
	3	1.488	61.11	61.11	100.00	0.00	



LAMPIRAN G

HASIL UJI DISOLUSI TABLET SUBLINGUAL PROPRANOLOL HIDROKLORIDA PADA t = 15 MENIT

Batch 1

formula	Tablet	Absorpsi	C sampel ($\mu\text{g/ml}$)	Wt (mg)	% obat terlarut
I	1	1.1858	67.6534	33.8267	86.5576
	2	1.1856	67.6404	33.8202	86.5409
	3	1.1867	67.7115	33.8557	86.6319
	4	1.1859	67.6598	33.8299	86.5658
	5	1.1863	67.6856	33.8428	86.5988
	6	1.1859	67.6598	33.8299	86.5658
II	1	1.1483	65.2321	32.6161	82.6811
	2	1.1747	66.9367	33.4684	84.8417
	3	1.1774	67.1109	33.5555	85.0625
	4	1.1677	66.4847	33.2424	84.2688
	5	1.1812	67.3563	33.6782	85.3735
	6	1.1709	66.6913	33.3457	84.5306
III	1	1.294	74.6395	37.3198	93.8814
	2	1.2705	73.1222	36.5611	91.973
	3	1.296	74.7686	37.3843	94.0438
	4	1.2897	74.3619	37.181	93.5323
	5	1.2974	74.859	37.4295	94.1575
	6	1.2705	73.1222	36.5611	91.973
IV	1	1.296	74.7686	37.3843	94.4811
	2	1.2355	70.8623	35.4312	89.545
	3	1.2898	74.3683	37.1842	93.9753
	4	1.2254	70.2102	35.1051	88.7209
	5	1.2355	70.8623	35.4312	89.545
	6	1.2993	74.9817	37.4909	94.7504

Batch II

formula	Tablet	Absorbsi	C sampel ($\mu\text{g/ml}$)	Wt (mg)	% obat terlarut
I	1	1.1858	67.6534	33.8267	84.2131
	2	1.1858	67.6534	33.8267	84.2131
	3	1.1867	67.7115	33.8558	84.2854
	4	1.1859	67.6598	33.8299	84.221
	5	1.1863	67.6856	33.8428	84.2531
	6	1.1859	67.6598	33.8299	84.221
II	1	1.1344	64.3346	32.1673	81.5436
	2	1.1016	62.2168	31.1084	78.8593
	3	1.1969	68.3701	34.1851	86.6585
	4	1.1922	68.0666	34.0333	86.2738
	5	1.1942	68.1957	34.0979	86.4375
	6	1.1804	67.3047	33.6524	85.3081
III	1	1.2915	74.4781	37.2391	93.6784
	2	1.2856	74.0971	37.0486	93.1992
	3	1.2939	74.6331	37.3166	93.8734
	4	1.2805	73.7679	36.884	92.7851
	5	1.2956	74.7428	37.3714	94.0114
	6	1.2676	72.9349	36.4675	91.7374
IV	1	1.2567	72.2312	36.1156	91.2748
	2	1.2554	72.1472	36.0736	91.1686
	3	1.2795	73.7032	36.8516	93.1349
	4	1.2355	70.8623	35.4312	89.545
	5	1.2993	74.9817	37.4909	94.7504
	6	1.296	74.7686	37.3843	94.4811

Batch III

formula	Tablet	Absorpsi	C sampel ($\mu\text{g/ml}$)	Wt (mg)	% obat terlarut
I	1	1.1647	66.291	33.1455	82.5172
	2	1.1812	67.3563	33.6782	83.8432
	3	1.1816	67.3822	33.6911	83.8755
	4	1.1717	66.7429	33.3715	83.0797
	5	1.1844	67.563	33.7815	84.1005
	6	1.1722	66.7752	33.3876	83.1199
II	1	1.1448	65.0061	32.5031	82.3947
	2	1.1447	64.9996	32.4998	82.3864
	3	1.1549	65.6582	32.8291	83.2212
	4	1.1459	65.0771	32.5386	82.4847
	5	1.1548	65.6518	32.8259	83.2131
	6	1.1556	65.7034	32.8517	83.2785
III	1	1.2635	72.6702	36.3351	91.8295
	2	1.2965	74.8009	37.4005	94.522
	3	1.2705	73.1222	36.5611	92.4007
	4	1.2815	73.8324	36.9162	93.2981
	5	1.2832	73.9422	36.9711	93.4369
	6	1.2845	74.0261	37.0131	93.5429
IV	1	1.3046	75.3239	37.662	95.1828
	2	1.2355	70.8623	35.4312	89.545
	3	1.3046	75.3239	37.662	95.1828
	4	1.2795	73.7032	36.8516	93.1349
	5	1.329	76.8994	38.4497	97.1737
	6	1.2567	72.2312	36.1156	91.2748

LAMPIRAN H
CONTOH PERHITUNGAN

Contoh perhitungan sudut diam:

Formula A:

$$W \text{ persegi panjang} = 4,92 \text{ gram}$$

$$W \text{ lingkaran} = 1,062 \text{ gram}$$

$$\text{Luas persegi panjang} = 712,8 \text{ cm}^2$$

$$\text{Luas lingkaran} = \frac{1,062}{4,92} \times 712,8 = 153,86 \text{ cm}^2$$

$$L = \pi \cdot r^2$$

$$r^2 = \frac{L}{\pi}$$

$$= \frac{153,86}{3,14}$$

$$r = 7 \text{ cm}$$

$$\text{tg } \alpha = \frac{t}{r} = \frac{2,5}{7}$$

$$= 27,32^\circ$$

Contoh perhitungan indeks kompresibilitas:

Formula A :

$$\text{Berat gelas} = 111,33 \text{ g (W}_1\text{)}$$

$$\text{Berat gelas + granul} = 177,5 \text{ g (W}_2\text{)}$$

$$V_1 = 100 \text{ ml}$$

$$V_2 = 81 \text{ m}$$

$$\text{Bj nyata} = \frac{(W_2 - W_1)}{V_1} = \frac{(177,5 - 111,33)}{100} = 0,6617$$

$$\text{Bj mampat} = \frac{(W_2 - W_1)}{V_2} = \frac{(177,5 - 111,33)}{81} = 0,8169$$

$$\% \text{ kompresibilitas} = \left(1 - \frac{\text{Bj.nyata}}{\text{Bj.mampat}}\right) \times 100\% = 19\%$$

Contoh perhitungan akurasi & presisi:

%	Bahan Aktif (mg)	Matriks (mg)	Aquadest	Pipet	Aquadest	Konsentrasi (µg/ml)
100	40	260	50	0,32	5	51,2

$$\text{Absorbansi} = 1.378 \rightarrow y = 0,0114x + 0,7918$$

$$\text{Konsentrasi sebenarnya} = 51.4575 \text{ ppm}$$

$$\text{Konsentrasi teoritis} = 51.4560 \text{ ppm}$$

$$\% \text{ perolehan kembali} = (\text{konsentrasi sebenarnya} / \text{konsentrasi teoritis}) \times$$

$$100\%$$

$$= (51.4575 / 51.4560) \times 100\%$$

$$= 100\%$$

$$\text{Untuk menghitung \% KV} = \frac{SD}{\bar{X}} \times 100\%$$

$$\% \text{ obat yang terlarut} = \frac{Wt}{40} \times 100\%$$

LAMPIRAN I
SERTIFIKAT ANALISIS PROPRANOLOL HIDROKLORIDA



Plant Jakarta
Rawagelam V No.1 Kawasan Industri Pulogadung
Telp. +62 21 4609354, 4603144 Fax. + 62 21 4603143
e.mail : dpj@cbn.net.id
Jakarta Timur 13930

No.Pemeriksaan : 80977/BB/08/02
Tgl.Permohonan : 14 Mei 2010
Tgl.Pemeriksaan : 03 Juni 2010
C.A : Ada

07 JUN 2010

Periksa laporan HPL No : 80977/BB/08 - 01

HASIL PEMERIKSAAN BAHAN BAKU

NAMA BAHAN BAKU	: PROPRANOLOL HCL (1000302) PROPRANOLOL HCL	TGL.PEMBUATAN	: Mei 2008
MEREK/PRODUSEN	: Societa Italiana Medicine Scandicci Italy	DALUARSA	: Mei 2013
JUMU KEMASAN	: 7 drum @ 25 kg = 175 kg	PEMASOK	: PT.Menjangan Sakti
Jumlah CONTOH	: 4 x 10 g (1 - 4)	No.BATCH	: 28.051

Pemeriksaan	Hasil	Syarat	Metode
Pemerian	1 - 4 = Serbuk kristal halus berwarna putih	Serbuk berwarna putih atau hampir putih	BP. 2003
Identifikasi	1 - 4 = Benar	-	BP. 2003
Kejernihan dan warna larutan(2 gram dalam 20 ml Methanol)	Memenuhi Pengujian	-	MPK0007
Susut pengeringan (10 ^o C konstan)	0,01%	Max,0,5 %	BP. 2003
Kadar	99,74%	-	BP. 2003
Kadar terhadap zat kering	99,75%	99,0 % - 101,0 %	BP. 2003

Kesimpulan : **DILULUSKAN/DITOLAK** Putri
Catatan : **Bagian Pergudangan**
Diperiksa ulang
Tgl. 04 Juni 2010

Apoteker Penanggung Jawab PM

Dra. Tia Mutianingsih

Jakarta, Asman Pengawasan Mutu

Drs. Hadi Kardoko

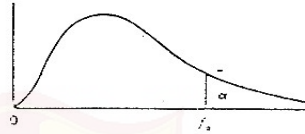
Y:\Industri\Bak. Sakel. Bina\DATA\MANAGER\PPIC\2010\INVENTARIS\BAGUM BR.doc

Jl. Rawagelam V No. 1
Kawasan Industri Pulogadung
Jakarta Timur 13930
Telp. 4609354 (Hunting), 4603144
Fax. 4603143

LAMPIRAN J

TABEL F

Tabel 7 Nilai kritis distribusi F



$f_{0,05}(v_1, v_2)$

v_2	v_1								
	1	2	3	4	5	6	7	8	9
1	161.4	199.5	215.7	224.6	230.2	234.0	236.8	238.9	240.5
2	18.51	19.00	19.16	19.25	19.30	19.33	19.35	19.37	19.38
3	10.13	9.55	9.28	9.12	9.01	8.94	8.89	8.85	8.81
4	7.71	6.94	6.59	6.39	6.26	6.16	6.09	6.04	6.00
5	6.61	5.79	5.41	5.19	5.05	4.95	4.88	4.82	4.77
6	5.99	5.14	4.76	4.53	4.39	4.28	4.21	4.15	4.10
7	5.59	4.74	4.35	4.12	3.97	3.87	3.79	3.73	3.68
8	5.32	4.46	4.07	3.84	3.69	3.58	3.50	3.44	3.39
9	5.12	4.26	3.86	3.63	3.48	3.37	3.29	3.23	3.18
10	4.96	4.10	3.71	3.48	3.33	3.22	3.14	3.07	3.02
11	4.84	3.98	3.59	3.36	3.20	3.09	3.01	2.95	2.90
12	4.75	3.89	3.49	3.26	3.11	3.00	2.91	2.85	2.80
13	4.67	3.81	3.41	3.18	3.03	2.92	2.83	2.77	2.71
14	4.60	3.74	3.34	3.11	2.96	2.85	2.76	2.70	2.65
15	4.54	3.68	3.29	3.06	2.90	2.79	2.71	2.64	2.59
16	4.49	3.63	3.24	3.01	2.85	2.74	2.66	2.59	2.54
17	4.45	3.59	3.20	2.96	2.81	2.70	2.61	2.55	2.49
18	4.41	3.55	3.16	2.93	2.77	2.66	2.58	2.51	2.46
19	4.38	3.52	3.13	2.90	2.74	2.63	2.54	2.48	2.42
20	4.35	3.49	3.10	2.87	2.71	2.60	2.51	2.45	2.39
21	4.32	3.47	3.07	2.84	2.68	2.57	2.49	2.42	2.37
22	4.30	3.44	3.05	2.82	2.66	2.55	2.46	2.40	2.34
23	4.28	3.42	3.03	2.80	2.64	2.53	2.44	2.37	2.32
24	4.26	3.40	3.01	2.78	2.62	2.51	2.42	2.36	2.30
25	4.24	3.39	2.99	2.76	2.60	2.49	2.40	2.34	2.28
26	4.23	3.37	2.98	2.74	2.59	2.47	2.39	2.32	2.27
27	4.21	3.35	2.96	2.73	2.57	2.46	2.37	2.31	2.25
28	4.20	3.34	2.95	2.71	2.56	2.45	2.36	2.29	2.24
29	4.18	3.33	2.93	2.70	2.55	2.43	2.35	2.28	2.22
30	4.17	3.32	2.92	2.69	2.53	2.42	2.33	2.27	2.21
40	4.08	3.23	2.84	2.61	2.45	2.34	2.25	2.18	2.12
60	4.00	3.15	2.76	2.53	2.37	2.25	2.17	2.10	2.04
120	3.92	3.07	2.68	2.45	2.29	2.17	2.09	2.02	1.96
∞	3.84	3.00	2.60	2.37	2.21	2.10	2.01	1.94	1.88

† Disalin dari Tabel 18 *Biometrika Tables for Statisticians*, Jilid I seizin E. S. Pearson dan *Biometrika Trustees*.

LAMPIRAN K

TABEL UJI R

DEGREES OF FREEDOM (DF)	5 PERCENT	1 PERCENT	DEGREES OF FREEDOM (DF)	5 PERCENT	1 PERCENT
1	.997	1.000	24	.388	.496
2	.950	.990	25	.381	.487
3	.878	.959	26	.374	.478
4	.811	.917	27	.367	.470
5	.754	.874	28	.361	.463
6	.707	.834	29	.355	.456
7	.666	.798	30	.349	.449
8	.632	.765	35	.325	.418
9	.602	.735	40	.304	.393
10	.576	.708	48	.288	.372
11	.553	.684	50	.273	.354
12	.532	.661	60	.250	.325
13	.514	.641	70	.232	.302
14	.497	.623	80	.217	.283
15	.482	.606	90	.205	.267
16	.468	.590	100	.195	.254
17	.456	.575	125	.174	.228
18	.444	.561	150	.159	.208
19	.433	.549	200	.138	.181
20	.423	.537	300	.113	.148
21	.413	.526	400	.098	.128
22	.404	.515	500	.088	.115
23	.396	.505	1000	.062	.081

Dikutip dari: Soedigdo & Soedigdo (1977)

LAMPIRAN L
HASIL UJI ANAVA KEKERASAN TABLET DENGAN *DESIGN*
EXPERT

Response 1 Kekerasan
ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob >F	
Model	7.30	3	2.43	88.43	< 0.0001	significant
<i>A-Avicel</i>	3.50	1	3.50	127.17	< 0.0001	
<i>B-SSG</i>	3.06	1	3.06	111.22	< 0.0001	
<i>AB</i>	0.74	1	0.74	26.89	0.0008	
Pure Error	0.22	8	0.028			
Cor Total	7.52	11				

The Model F-value of 88.43 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant.

In this case A, B, AB are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.17	R-Squared	0.9707
Mean	6.22	Adj R-Squared	0.9597
C.V. %	2.67	Pred R-Squared	0.9341
PRESS	0.50	Adeq Precision	21.823

The "Pred R-Squared" of 0.9341 is in reasonable agreement with the "Adj R-Squared" of 0.9597.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your ratio of 21.823 indicates an adequate signal. This model can be used to

navigate the design space.

Factor	Coefficient	Standard	95% CI	95% CI	High	VIF
	Estimate	df	Error	Low		
Intercept	6.22	1	0.048	6.11	6.33	
A-Avicel	0.54	1	0.048	0.43	0.65	1.00
B-SSG	-0.51	1	0.048	-0.62	-0.39	1.00
AB	0.25	1	0.048	0.14	0.36	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \text{Kekerasan} &= \\ &+6.22 \\ &+0.54 * A \\ &-0.51 * B \\ &+0.25 * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \text{Kekerasan} &= \\ &+6.68000 \\ &+6.30556E-003 * \text{Avicel} \\ &-0.41667 * \text{SSG} \\ &+4.13889E-003 * \text{Avicel} * \text{SSG} \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node.

In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for

constant error.

3) Externally Studentized Residuals to look for outliers, i.e., influential values.

4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.



LAMPIRAN M
HASIL UJI ANAVA KERAPUHAN TABLET DENGAN *DESIGN*
EXPERT

Response 2 Kerapuhan
ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	0.40	3	0.13	617.25	< 0.0001
<i>A-Avicel</i>	0.28	1	0.28	1295.78	< 0.0001
<i>B-SSG</i>	0.090	1	0.090	411.31	< 0.0001
<i>AB0.032</i>		1	0.032	144.66	< 0.0001
Pure Error	1.745E-003	8		2.181E-004	
Cor Total	0.41	11			

The Model F-value of 617.25 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant.

In this case A, B, AB are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.015	R-Squared	0.9957
Mean	0.27	Adj R-Squared	0.9941
C.V. %	5.48	Pred R-Squared	0.9903
PRESS	3.926E-003	Adeq Precision	56.278

The "Pred R-Squared" of 0.9903 is in reasonable agreement with the "Adj R-Squared" of 0.9941.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your

ratio of 56.278 indicates an adequate signal. This model can be used to

navigate the design space.

Factor	Coefficient		Standard Error	95% CI	
	Estimate	df		Low	High
Intercept	0.27	1	4.263E-003	0.26	0.28
A-Avicel	-0.15	1	4.263E-003	-0.16	-0.14
B-SSG	0.086	1	4.263E-003	0.077	0.096
AB	-0.051	1	4.263E-003	-0.061	-0.041

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \text{Kerapuhan} &= \\ &+0.27 \\ &-0.15 \quad * A \\ &+0.086 \quad * B \\ &-0.051 \quad * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \text{Kerapuhan} &= \\ &+0.32921 \\ &-3.40000\text{E-}003 \quad * \text{Avicel} \\ &+0.080094 \quad * \text{SSG} \\ &-8.54583\text{E-}004 \quad * \text{Avicel} * \text{SSG} \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node.
In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential

values.

4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.



LAMPIRAN N
HASIL UJI ANAVA WAKTU HANCUR TABLET DENGAN *DESIGN*
EXPERT

Response 3 Waktu hancur
ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	23.53	3	7.84	537.77	< 0.0001
<i>A-Avicel</i>	5.88	1	5.88	403.20	< 0.0001
<i>B-SSG</i>	17.28	1	17.28	1184.91	<0.0001
<i>AB0.37</i>		1	0.37	25.20	0.0010
Pure Error		8	0.12	0.015	
Cor Total	23.64	11			

The Model F-value of 537.77 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant.

In this case A, B, AB are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.12	R-Squared	0.9951
Mean	3.09	Adj R-Squared	0.9932
C.V. %	3.91	Pred R-Squared	0.9889
PRESS	0.26	Adeq Precision	54.502

The "Pred R-Squared" of 0.9889 is in reasonable agreement with the "Adj R-Squared" of 0.9932.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your

ratio of 54.502 indicates an adequate signal. This model can be used to

navigate the design space.

Factor	Coefficient		Standard Error	95% CI	
	Estimate	df		Low	High
Intercept	3.09	1	0.035	3.01	3.17
A-Avicel	0.70	1	0.035	0.62	0.78
B-SSG	-1.20	1	0.035	-1.28	1.12
AB	-0.17	1	0.035	-0.26	-0.095

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \text{Waktu hancur} &= \\ &+3.09 \\ &+0.70 \quad * A \\ &-1.20 \quad * B \\ &-0.17 \quad * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \text{Waktu hancur} &= \\ &+2.11667 \\ &+0.049583 \quad * \text{Avicel} \\ &-0.22500 \quad * \text{SSG} \\ &-2.91667\text{E-}003 \quad * \text{Avicel} * \text{SSG} \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node.

In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential

values.

4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.



LAMPIRAN O

HASIL UJI ANAVA PERSEN OBAT TERLARUT DALAM T = 15 MENIT DENGAN *DESIGN EXPERT*

Response 4. Disolusi

ANOVA for selected factorial model

Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	191.28	3	63.76	329.83	< 0.0001 significant
<i>A-Avicel</i>	47.70	1	47.70	246.78	< 0.0001
<i>B-SSG</i>	131.19	1	131.19	678.67	< 0.0001
<i>AB</i>	12.38	1	12.38	64.05	< 0.0001
Pure Error	1.55	8	0.19		
Cor Total	192.83	11			

The Model F-value of 329.83 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant.

In this case A, B, AB are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.44	R-Squared	0.9920
Mean	88.66	Adj R-Squared	0.9890
C.V. %	0.50	Pred R-Squared	0.9820
PRESS	3.48	Adeq Precision	41.761

The "Pred R-Squared" of 0.9820 is in reasonable agreement with the "Adj R-Squared" of 0.9890.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your

ratio of 41.761 indicates an adequate signal. This model can be used to navigate the design space.

Coefficient Factor	Standard Estimate	df	95% CI Error	95% CI Low	95% CI High	VIF
Intercept	88.66	1	0.13	88.37	88.95	
A-Avicel	-1.99	1	0.13	-2.29	-1.70	1.00
B-SSG	3.31	1	0.13	3.01	3.60	1.00
AB1.02	1	0.13	0.72	1.31	1.00	

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \text{Disolusi} &= \\ &+88.66 \\ &-1.99 * A \\ &+3.31 * B \\ &+1.02 * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \text{Disolusi} &= \\ &+94.20852 \\ &-0.18434 * \text{Avicel} \\ &+0.086379 * \text{SSG} \\ &+0.016930 * \text{Avicel} * \text{SSG} \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node.
In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
- 4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.



LAMPIRAN P
UJI F KURVA BAKU PENETAPAN KADAR
 Uji Kesamaan Regresi (Aquadest)

REPLIKASI 1

KONSENTRASI	ABSORBANSI	X²	Y²	XY
32.192	1.141	1036.3249	1.3019	36.7311
48.288	1.303	2331.7309	1.6978	62.9193
64.384	1.432	4145.2995	2.0506	92.1979
80.48	1.603	6477.0304	2.5696	129.0094
96.576	1.711	9326.9238	2.9275	165.2415
		23317.3094	10.5474	486.0992

REPLIKASI 2

KONSENTRASI	ABSORBANSI	X²	Y²	XY
32.064	0.957	1028.1001	0.9158	30.6852
48.096	1.103	2313.2252	1.2166	53.0499
64.128	1.232	4112.4004	1.5178	79.0057
80.16	1.423	6425.6256	2.0249	114.0677
96.192	1.551	9252.9009	2.4056	149.1938
		23132.2522	8.0808	426.0023

REPLIKASI 3

KONSENTRASI	ABSORBANSI	X²	Y²	XY
32.128	1.141	1032.2084	1.3019	36.6580
48.192	1.353	2322.4689	1.8306	65.2038
64.256	1.531	4128.8335	2.3440	98.3759
80.32	1.723	6451.3024	2.9687	138.3914
96.384	1.871	9289.8755	3.5006	180.3345
		23224.6886	11.9458	518.9636

	$S X^2$	SXY	$S Y^2$	N	SSi	RDF
Regresi I	23317.3094	486.0992	10.5474	5	10.5266	4
Regresi II	23132.2522	426.0023	8.0808	5	8.0624	4
Regresi III	23224.6886	518.9636	11.9458	5	11.9235	4
	69674.2502	1431.0651	30.5741		30.5125	

SSc = 30.55353763

F = 0.008075857 < F tabel (3,89)



LAMPIRAN Q

UJI F KURVA BAKU DISOLUSI

Uji Kesamaan Regresi (Dapar fosfat pH 6,8)

REPLIKASI 1

KONSENTRASI	ABSORBANSI	X ²	Y ²	XY
32.192	1.141	1036.3249	1.3019	36.7311
48.288	1.303	2331.7309	1.6978	62.9193
64.384	1.432	4145.2995	2.0506	92.1979
80.48	1.603	6477.0304	2.5696	129.0094
96.576	1.711	9326.9238	2.9275	165.2415
		23317.3094	10.5474	486.0992

REPLIKASI 2

KONSENTRASI	ABSORBANSI	X ²	Y ²	XY
32.064	0.957	1028.1001	0.9158	30.6852
48.096	1.103	2313.2252	1.2166	53.0499
64.128	1.232	4112.4004	1.5178	79.0057
80.16	1.423	6425.6256	2.0249	114.0677
96.192	1.551	9252.9009	2.4056	149.1938
		23132.2522	8.0808	426.0023

REPLIKASI 3

KONSENTRASI	ABSORBANSI	X ²	Y ²	XY
32.128	1.141	1032.2084	1.3019	36.6580
48.192	1.353	2322.4689	1.8306	65.2038
64.256	1.531	4128.8335	2.3440	98.3759
80.32	1.723	6451.3024	2.9687	138.3914
96.384	1.871	9289.8755	3.5006	180.3345
		23224.6886	11.9458	518.9636

	ΣX^2	ΣXY	ΣY^2	N	SSi	RDF
Regresi I	23317.3094	486.0992	10.5474	5	10.5266	4
Regresi II	23132.2522	426.0023	8.0808	5	8.0624	4
Regresi III	23224.6886	518.9636	11.9458	5	11.9235	4
	69674.2502	1431.0651	30.5741		30.5125	

SSc= 30.55353763
F= 0.008075857 < F_{tabel} 3,89

