BAB V

KESIMPULAN DAN SARAN

A. Kesimpulan

Kesimpulan yang diperoleh berdasarkan hasil penelitian dan data statistik terhadap uji sifat fisik tablet adalah:

1. Salbutamol dapat dibuat menjadi sediaan tablet dengan bahan pengikat polivinil pirolidon dan bahan penghancur explotab yang memenuhi persyaratan mutu fisik menurut Farmakope Indonesia dan pustaka lainnya.
2. Kombinasi polivinil pirolidon dan explotab 3% : 5% memberikan mutu fisik sediaan tablet salbutamol yang paling baik dibandingkan dengan kombinasi polivinil pirolidon dan explotab dengan perbandingan 4% : 4% dan 5% : 3%.

B. Saran

Saran dari penulis untuk penelitian pembuatan sediaan tablet salbutamol dengan perbandingan konsentrasi polivinpirolidon dan explotab adalah:

1. Perlu dilakukan penelitian lebih lanjut tentang pembuatan tablet salbutamol dengan metode yang berbeda.
2. Perlu dilakukannya pengembangan formula sediaan tablet salbutamol agar dapat ditingkatkan lagi mutu dari sediaan tablet salbutamol sehingga dapat dibuat dalam skala besar.

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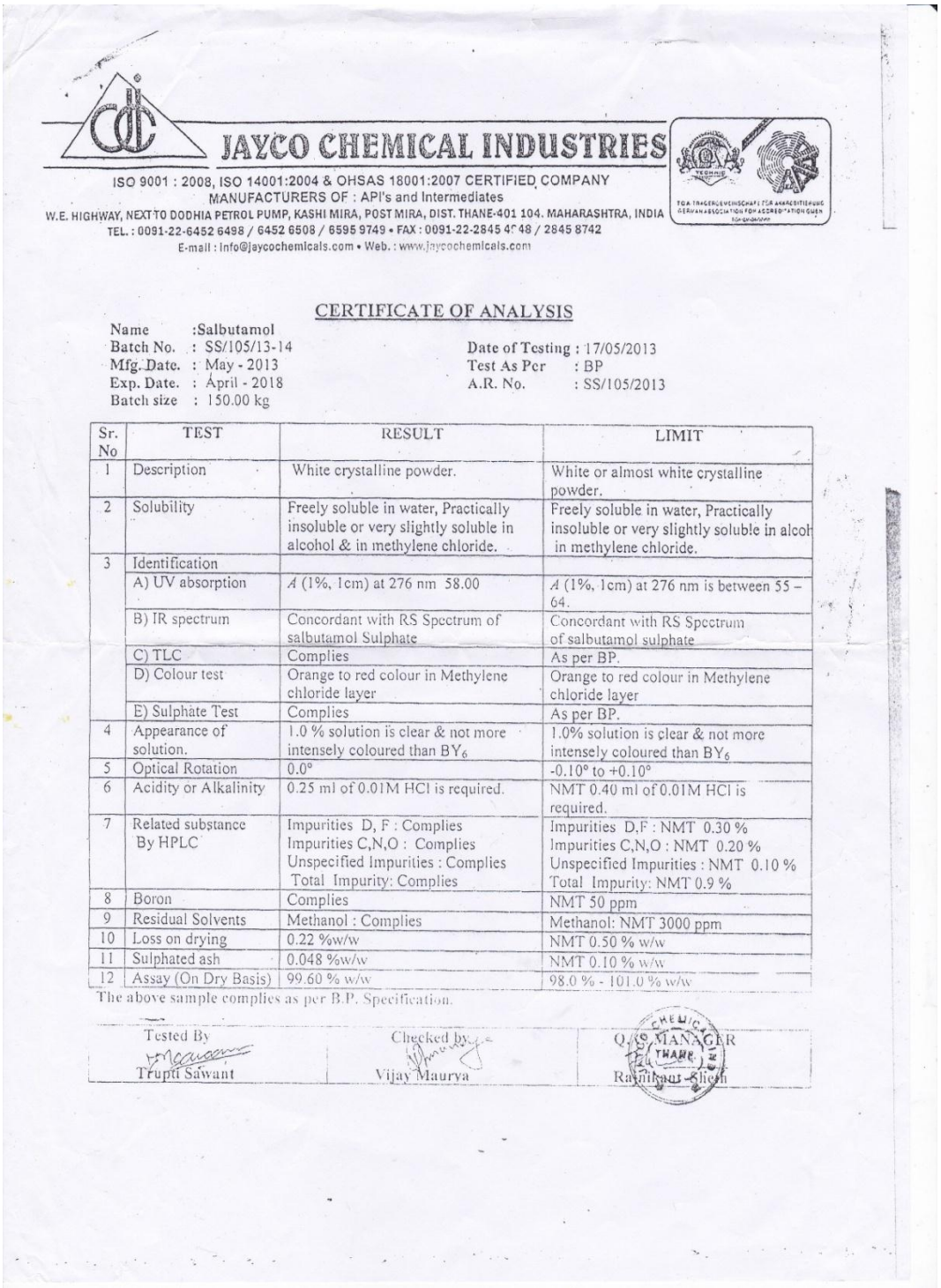
LAMPIRAN

Lampiran 1. Sertifikat analisis Salbutamol



JAYCO CHEMICAL INDUSTRIES

ISO 9001 : 2008, ISO 14001:2004 & OHSAS 18001:2007 CERTIFIED COMPANY
MANUFACTURERS OF : API's and Intermediates
W.E. HIGHWAY, NEXT TO DODHIA PETROL PUMP, KASHI MIRA, POST MIRA, DIST. THANE-401 104. MAHARASHTRA, INDIA
TEL. : 0091-22-6452 6498 / 6452 6508 / 6595 9749 • FAX : 0091-22-2845 4048 / 2845 8742
E-mail : info@jaycochemicals.com • Web. : www.jaycochemicals.com

CERTIFICATE OF ANALYSIS

Name :Salbutamol
Batch No. : SS/105/13-14
Mfg. Date. : May - 2013
Exp. Date. : April - 2018
Batch size : 150.00 kg

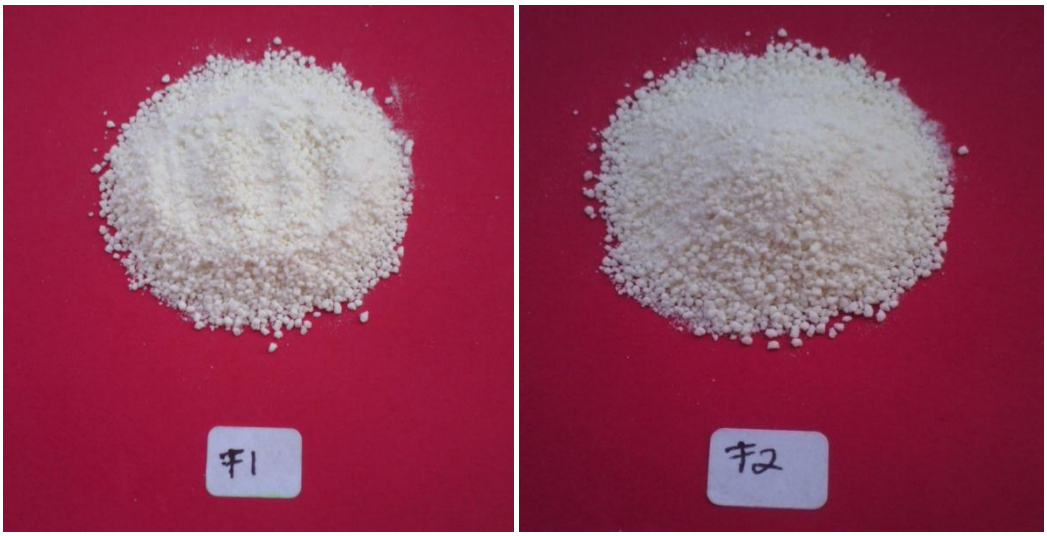
Date of Testing : 17/05/2013
Test As Per : BP
A.R. No. : SS/105/2013

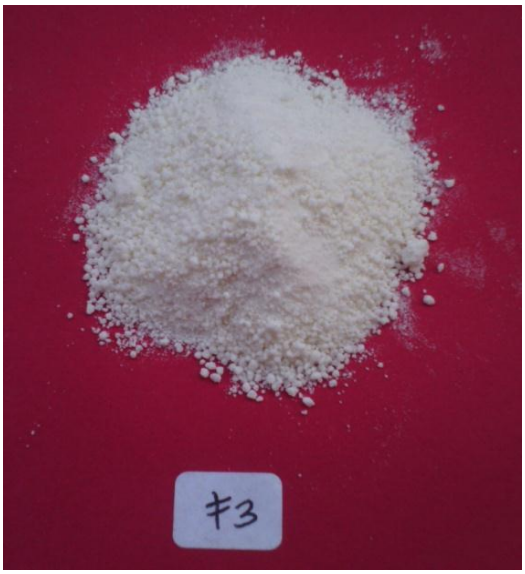
Sr. No	TEST	RESULT	LIMIT
1	Description	White crystalline powder.	White or almost white crystalline powder.
2	Solubility	Freely soluble in water, Practically insoluble or very slightly soluble in alcohol & in methylene chloride.	Freely soluble in water, Practically insoluble or very slightly soluble in alcoh in methylene chloride.
3	Identification		
	A) UV absorption	*A* (1%, 1cm) at 276 nm 58.00	*A* (1%, 1cm) at 276 nm is between 55 – 64.
	B) IR spectrum	Concordant with RS Spectrum of salbutamol Sulphate	Concordant with RS Spectrum of salbutamol sulphate
	C) TLC	Complies	As per BP.
	D) Colour test	Orange to red colour in Methylene chloride layer	Orange to red colour in Methylene chloride layer
	E) Sulphate Test	Complies	As per BP.
4	Appearance of solution.	1.0 % solution is clear & not more intensely coloured than BY_6	1.0% solution is clear & not more intensely coloured than BY_6
5	Optical Rotation	0.0°	-0.10° to +0.10°
6	Acidity or Alkalinity	0.25 ml of 0.01M HCl is required.	NMT 0.40 ml of 0.01M HCl is required.
7	Related substance By HPLC	Impurities D, F : Complies Impurities C,N,O : Complies Unspecified Impurities : Complies Total Impurity: Complies	Impurities D,F : NMT 0.30 % Impurities C,N,O : NMT 0.20 % Unspecified Impurities : NMT 0.10 % Total Impurity: NMT 0.9 %
8	Boron	Complies	NMT 50 ppm
9	Residual Solvents	Methanol : Complies	Methanol: NMT 3000 ppm
10	Loss on drying	0.22 %w/w	NMT 0.50 % w/w
11	Sulphated ash	0.048 %w/w	NMT 0.10 % w/w
12	Assay (On Dry Basis)	99.60 % w/w	98.0 % - 101.0 % w/w

The above sample complies as per B.P. Specification.

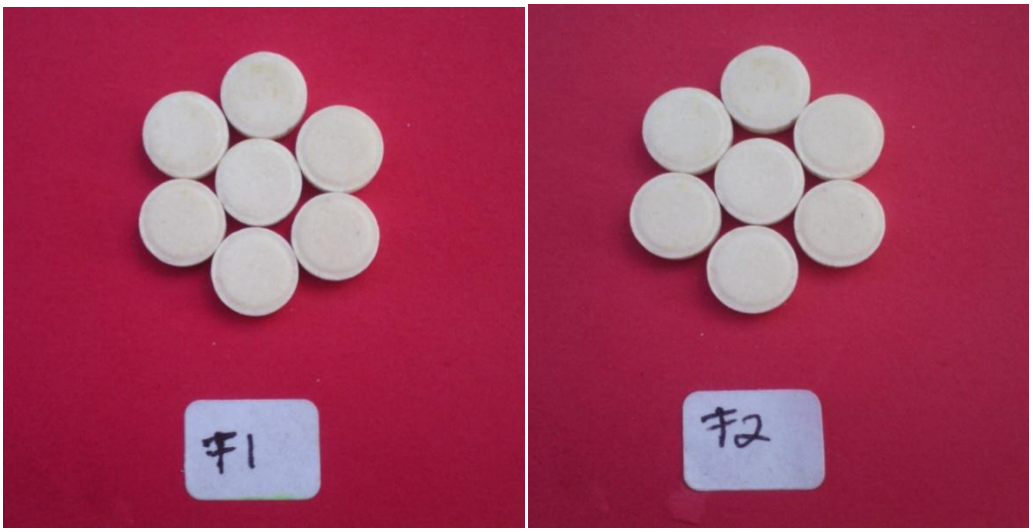
Tested By	Checked by	Q.C. MANAGER
Trupti Sawant	Vijay Maurya	Ramkisan Shirsath

Lampiran 2. Foto granul tablet salbutamol

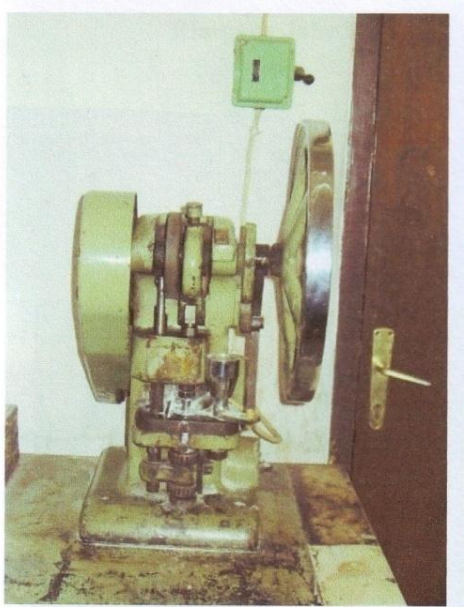




Lampiran 3. Foto sediaan tablet salbutamol

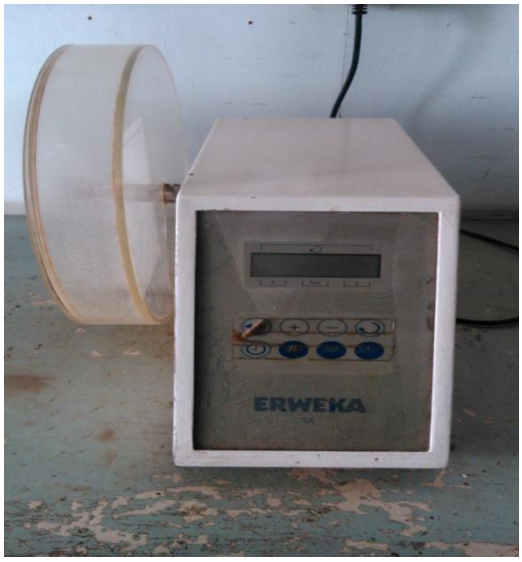


Lampiran 4. Foto alat penguji sedian tablet



Single punch

Hardness tester



Friability tester

Moisture Balance

Lampiran 5. Data waktu alir granul

No	Waktu Alir Granul (detik) Polivinilpirolidon : Explotab		
	F I (3% : 5%)	**F II (4% : 4%)**	**F III (5% : 3%)**
1.	6.41	5,31	4,38
2.	6,38	5,48	5,47
3.	7,42	5,37	5,28
4.	7,5	5,29	5,39
5.	7,31	4,47	4,45
6.	7,4	4,29	4,27
7.	6,32	5,44	4,19
8.	7,21	5,27	4,57
9.	6,58	5,29	4,21
10.	6,42	5,41	5,22
X	68,95	51,62	47,43
$\overline{\mathbf{x}}$	6,895	5,162	4,743
SD	0,5603	0,4201	0,5081

Perhitungan statistik

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Waktu alir	30	5.6000	1.05814	4.19	7.50

One-Sample Kolmogorov-Smirnov Test

		Waktu alir
N		30
Normal Parameters[a,b]	Mean	5.6000
	Std. Deviation	1.05814
Most Extreme Differences	Absolute	.212
	Positive	.212
	Negative	-.103
Kolmogorov-Smirnov Z		1.160
Asymp. Sig. (2-tailed)		.135

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

Waktu alir

Levene Statistic	df1	df2	Sig.
2.529	2	27	.098

ANOVA

Waktu alir

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	26.033	2	13.017	54.598	.000
Within Groups	6.437	27	.238		
Total	32.470	29			

Post Hoc Tests

Multiple Comparisons

Waktu alir

Scheffe

(I) Formula tablet	(J) Formula tablet	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	1.73300*	.21836	.000	1.1674	2.2986
	Formula	2.15200*	.21836	.000	1.5864	2.7176
Formula 2	Formula 1	-1.73300*	.21836	.000	-2.2986	-1.1674
	Formula	.41900	.21836	.178	-.1466	.9846
Formula	Formula 1	-2.15200*	.21836	.000	-2.7176	-1.5864
	Formula 2	-.41900	.21836	.178	-.9846	.1466

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

Homogeneous Subsets

Waktu alir

Scheffe[a]

Formula tablet	N	Subset for alpha = 0.05	
		1	2
Formula	10	4.7430	
Formula 2	10	5.1620	
Formula 1	10		6.8950
Sig.		.178	1.000

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Lampiran 6. Data susut pengeringan granul

Berat (gram)	**Konsentrasi Polivinilpirolidon : Explotab**		
	F I	**F II**	**F III**
	(3% : 5%)	**(4% : 4%)**	**(5% : 3%)**
Berat mula-mula	2,00	2,00	2,00
Berat konstan	1,92	1,91	1,93
LOD %	4,00%	4,50%	3,50%

Contoh perhitungan LOD

% LOD = $\frac{2-1,92}{2}$ x 100%

= 4,00%

Lampiran 7. Formulasi tablet salbutamol

Bahan (mg)	**Formula (mg)**		
	F I (3% : 5%)	**F II (4% : 4%)**	**F III (5% : 3%)**
Salbutamol	4	4	4
Explotab	10	8	6
Polivinil pirolidon	6	8	10
Mg stearat	2	2	2
Laktosa	178	178	178
Bobot tablet	200	200	200

Keterangan : FI (Polivinilpirolidon 3% : Explotab 5%)
FII (Polivinilpirolidon 4% : Explotab 4%)
FIII (Polivinilpirolidon 5% : Explotab 3%)

Perhitungan bahan pembuatan 100 tablet:

Polivinilpirolidon 3% = $\frac{3}{100}$ x 200 = 6 x 100 = 600 mg

Polivinilpirolidon 4% = $\frac{4}{100}$ x 200 = 8 x 100 = 800 mg

Polivinilpirolidon 5% = $\frac{5}{100}$ x 200 = 10 x 100 = 1000 mg

Explotab 3% = $\frac{3}{100}$ x 200 = 6 x 100 = 600 mg

Explotab 4% = $\frac{4}{100}$ x 200 = 8 x 100 = 800 mg

Explotab 5% = $\frac{5}{100}$ x 200 = 10 x 100 = 1000

Mg stearat = 2 x 100 = 200 mg

Laktosa = 178 x 100 = 17800 mg

Lampiran 8. Data uji keseragaman bobot tablet.

No.	Bobot tablet (mg) Polovinilpirolidon : Explotab		
	F1 (3% : 5%)	**F2 (4% : 4%)**	**F3 (5% : 3%)**
1.	202	199	200
2.	200	206	203
3.	196	207	199
4.	202	204	200
5.	197	211	199
6.	199	197	202
7.	199	197	203
8.	203	200	197
9.	198	207	201
10.	203	205	203
11.	201	200	202
12.	200	200	201
13.	199	207	197
14.	199	203	201
15.	200	209	205
16.	196	199	199
17.	198	204	198
18.	200	198	201
19.	198	202	200
20.	199	197	201
X	3989	4052	4012
$\overline{X}$	199,45	202,6	200,6
SD	2,038 %	2,125%	2,087%
CV	1,02%	1,04%	1,04%
$\overline{x}$ + 7,5%	214,4088	217,795	215,645
$\overline{x}$ – 7,5%	184,4913	187,405	185,555
$\overline{x}$+15%	229,3675	232,99	230,69
$\overline{x}$-15%	169,5325	172,21	170,51

Perhitungan statistik

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Keseragaman bobot	60	201.4167	4.79156	191.00	213.00

One-Sample Kolmogorov-Smirnov Test

		Keseragaman bobot
N		60
Normal Parameters[a,,b]	Mean	201.4167
	Std. Deviation	4.79156
Most Extreme Differences	Absolute	.100
	Positive	.100
	Negative	-.062
Kolmogorov-Smirnov Z		.771
Asymp. Sig. (2-tailed)		.591

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

Keseragaman bobot

Levene Statistic	df1	df2	Sig.
7.106	2	57	.002

ANOVA

Keseragaman bobot

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	59.733	2	29.867	1.315	.277
Within Groups	1294.850	57	22.717		
Total	1354.583	59			

Lampiran 9. Data uji kekerasan tablet

No.	Kekerasan tablet (kg) Polivinilpirolidon : Explotab		
	F I (3% : 5%)	**F II (4% : 4%)**	**F III (5% : 3%)**
1.	8,4	10,3	11,2
2.	9	10,7	10,1
3.	8,5	10,8	10,1
4.	9,3	10,9	10,8
5.	9,6	10,1	12
6.	10,5	9,8	10,4
7.	10,2	11,3	10,8
8.	10,8	8,9	12
9.	10,5	10,9	11,8
10.	10,8	11,1	9,8
X	97,6	104,8	109
$\bar{x}$	9,76	10,48	10,9
SD	0,6367	0,4971	0,5656

Perhitungan statistik

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Kekerasan tablet	30	10.3800	.93085	8.40	12.00

One-Sample Kolmogorov-Smirnov Test

		Kekerasan tablet
N		30
Normal Parameters[a,,b]	Mean	10.3800
	Std. Deviation	.93085
Most Extreme Differences	Absolute	.115
	Positive	.088
	Negative	-.115
Kolmogorov-Smirnov Z		.631
Asymp. Sig. (2-tailed)		.821

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

Kekerasan tablet

Levene Statistic	df1	df2	Sig.
.879	2	27	.427

ANOVA

Kekerasan tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	6.648	2	3.324	4.856	.016
Within Groups	18.480	27	.684		
Total	25.128	29			

Post Hoc Tests

Multiple Comparisons

Kekerasan tablet

Scheffe

(I) Formula tablet	(J) Formula tablet	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	.42000	.36998	.533	-.5383	1.3783
	Formula 3	1.14000*	.36998	.017	.1817	2.0983
Formula 2	Formula 1	-.42000	.36998	.533	-1.3783	.5383
	Formula 3	.72000	.36998	.170	-.2383	1.6783
Formula 3	Formula 1	-1.14000*	.36998	.017	-2.0983	-.1817
	Formula 2	-.72000	.36998	.170	-1.6783	.2383

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

Homogeneous Subsets

Kekerasan tablet

Scheffe[a]

Formula tablet	N	Subset for alpha = 0.05	
		1	2
Formula 3	10	9.7600	
Formula 2	10	10.4800	10.4800
Formula 1	10		10.9000
Sig.		.170	.533

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Lampiran 10. Data uji kerapuhan tablet

Berat tablet (g)	**Polivinilpirolidon : Explotab**								
	F I (3% : 5%)			**F II (4% : 4%)**			**F III (5% : 3%)**		
	1	2	3	1	2	3	1	2	3
Sebelum	3,8714	4,2145	3,9186	4,0352	4,1087	4,1102	4,0352	4,1087	4,1102
Sesudah	3,852	4,1937	3,899	4,0165	4,0897	4,0918	4,0165	4,0897	4,0918
Kerapuhan %	0,5%	0,49%	0,5%	0,46%	0,46%	0,44%	0,46%	0,44%	0,44%
	x = 1,49%			x = 1,36%			x = 1,34%		
	$\bar{x}$ = 0,49 %			$\bar{x}$ = 0,45%			$\bar{x}$ = 0,44%		
	SD = 0,007			SD = 0,012			SD = 0,014		

Contoh perhitungan % kerapuhan tablet = 0,50%

- Berat 20 tablet yang sudah dibebasdebukan = 3,8714 gram
- Berat 20 tablet setelah perlakuan = 3,852 gram
- % kerapuhan = $\frac{\text{berat awal – berat setelah perlakuan}}{\text{berat awal}}$ X 100 %

$$= \frac{3,8714-3,852}{3,8714} \text{ x } 100\%$$

= 0,50%

Perhitungan statistik

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
kerapuhan tablet	9	.3138	.23251	.00	.50

One-Sample Kolmogorov-Smirnov Test

		kerapuhan tablet
N		9
Normal Parameters[a,b]	Mean	.3138
	Std. Deviation	.23251
Most Extreme Differences	Absolute	.373
	Positive	.241
	Negative	-.373
Kolmogorov-Smirnov Z		1.119
Asymp. Sig. (2-tailed)		.163

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

kerapuhan tablet

Levene Statistic	df1	df2	Sig.
.040	2	6	.961

ANOVA

kerapuhan tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.002	2	.001	.010	.990
Within Groups	.431	6	.072		
Total	.432	8			

Lampiran 11. Data uji waktu hancur tablet

No.	**Waktu hancur (menit)**		
	Polivinilpirolidon : Explotab		
	F1	**F2**	**F3**
	(3% : 5%)	**(4% : 4%)**	**(5% : 3%)**
1.	6,19	6,59	7,24
2.	6,21	7,01	7,28
3.	6,25	7,09	7,28
4.	6,27	7,1	7,31
5.	6,27	7,13	7,49
6.	6,29	7,15	7,57
x	37,48	42,07	44,17
$\bar{x}$	6,24	7,01	7,36
SD	0,0015	0,0449	0,0181

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Waktu hancur	18	412.4000	29.91163	371.40	454.20

One-Sample Kolmogorov-Smirnov Test

		Waktu hancur
N		18
Normal Parameters[a,b]	Mean	412.4000
	Std. Deviation	29.91163
Most Extreme Differences	Absolute	.224
	Positive	.212
	Negative	-.224
Kolmogorov-Smirnov Z		.949
Asymp. Sig. (2-tailed)		.329

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

Waktu hancur

Levene Statistic	df1	df2	Sig.
2.394	2	15	.125

ANOVA

Waktu hancur

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	14046.840	2	7023.420	90.573	.000
Within Groups	1163.160	15	77.544		
Total	15210.000	17			

Post Hoc Tests

Multiple Comparisons

Waktu hancur

Scheffe

(I) Formula tab	(J) Formula tab	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
FORMULA 1	FORMULA 2	-45.90000*	5.08409	.000	-59.6971	-32.1029
	FORMULA 3	-66.90000*	5.08409	.000	-80.6971	-53.1029
FORMULA 2	FORMULA 1	45.90000*	5.08409	.000	32.1029	59.6971
	FORMULA 3	-21.00000*	5.08409	.003	-34.7971	-7.2029
FORMULA 3	FORMULA 1	66.90000*	5.08409	.000	53.1029	80.6971
	FORMULA 2	21.00000*	5.08409	.003	7.2029	34.7971

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

Homogeneous Subsets

Waktu hancur

Scheffe[a]

Formula tab	N	Subset for alpha = 0.05		
		1	2	3
FORMULA 1	6	374.8000		
FORMULA 2	6		420.7000	
FORMULA 3	6			441.7000
Sig.		1.000	1.000	1.000

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 6.000.