BAB V

KESIMPULAN DAN SARAN

A. Kesimpulan

Kesimpulan yang didapat berdasarkan hasil penelitian dan data statistik terhadap uji mutu fisik kapsul adalah:

1. Formulasi sediaan tablet salbutamol dengan variasi konsentrasi Na-CMC dan Explotab® dapat menghasilkan sediaan tablet yang memenuhi syarat uji mutu fisik tablet.
2. Formula I dengan variasi konsentrasi Na-CMC 3% dan Explotab® 5% merupakan formula yang paling baik dibandingkan formula II dan formula III.

B. Saran

Saran dari penulis untuk penelitian pembuatan sediaan tablet salbutamol dengan perbandingan konsentrasi Na-CMC dan Explotab® adalah:

1. Perlu dilakukan penelitian lebih lanjut dengan menggunakan bahan pengikat dan bahan penghancur lain serta dengan metode yang berbeda.
2. Perlu dilakukan pengembangan formula sehingga penelitian ini dapat lebih baik lagi dan dapat dilakukan dalam skala besar atau digunakan dalam skala industri.

DAFTAR PUSTAKA

Ansel, H.C. 1989. *Pengantar Bentuk Sediaan Formulasi*, Edisi IV. Universitas Indonesia. Jakarta: Hlm 245-272.

Banker, S.G. and Anderson, R.N, 1986, Tablet, in Lachman, L. Lieberman, H. A., and Kanig, J. L., The *Theory And Practice Of Industrial Pharmacy*, 3rd Ed., Lea and Febiger, Philadelphia. Hlm 644

Departemen kesehtan RI. 1979. *Farmakope indonesia edisi III*. Jakarta: departemen kesehatan republik indonesia. Hlm 6-7

Departemen kesehatan RI. 1995. *Farmakope Indonesia*, Edisi IV, Departemen Kesehatan Republik Indonesia. Jakarta: Hlm 248-250, 456-457

Edge and Miller. 2006. *sodium strach glycolate.* In rowe, RC Sheskey, PJ and owen SC(Eds), Handbook of *pharmaceutical Exipients*. 5th Ed. London : Pharmceutical Press. Hlm 701-703

Fennema, O.R. M. Karen, and D. B. Lund. 1996. *Principle of Food Science*. The AVI Publishing, Connecticut http://en.wikipedia.org/wiki/Cellulose. [18 oktober 2013]

Fonner, D.E. Anderson, N.R., Banker, C.S., 1981, Granulation and Tablet Characteristic in Lieberman, H.A., Lachman, L., (Eds.), Pharmaceutical Dosage Form: Tablet, vol. 2, Mercel Dekker inc., New York: Hlm 226-231

Kurniawan, A. 2013. *Optimasi Formula Tablet Lepas Lambat Salbutamol sulfat Menggunakan Matrik Xanthan Gum Na-CMC Dengan Metode Simplex lattic Design.* [KTI], Surakarta: Fakultas Farmasi, universitas setia budi. Hal 19-21

Kuswardani, W. 2012. *Pembuatan tablet hisap vitamin c dengan bahan pengikat polivinilpirolidon secara kempa langsung*. [KTI], Surakarta: Fakultas Farmasi, universitas setia budi. Hal 7

Lachman, H.L. Lieberman, H.A, Kanig J.L 1986, *The Theory and Practice of Industrial Pharmacy*, Third edition, Lea and Febiger, Philadelphia: 297-301, 314-218.

Lachman, C.L. Lieberman, H.H, Kaning, J.L 1994, *Teori dan Praktek Farmasi Industri.* Indonesia University Press. Jakarta: Hlm 644-646, 681-690, 697-703

Parrott, E.L. 1971. *Pharmaceutical Technology Fundamental Pharmaceutics*, 3rd Ed., Burgess Publishing Company, Minnepolis: 64-66, 73-83

Puratchikody A, Prasanth VV, Mathew ST, Kumar BA. 2011. Development and Characterization of Mucoadhesive Patches of Salbutamol for Unidirectional Buccal Drug Delivery.*Acta Pharmaceutical.*61: 157–170.

Ridhani, M. J. 2013. *Formulasi Sediaan Kapsul Kulit Apel Rome Beauty (malussylvestris, Mill) Sebagai Antioksidan Dengan Variasi Pengikat Polivinil Pirolidon.* [KTI], Surakarta: Fakultas Farmasi, universitas setia budi. Hal 18

Tjay H.T, dan Raharja, K. 1986, *Obat-Obat Penting*. Edisi IV. Jakarta: Hlm 479-480

Tjay H.T, dan Raharja, K. 2002, *Obat-Obat Penting*. Edisi V. Jakarta: Hlm 638-651

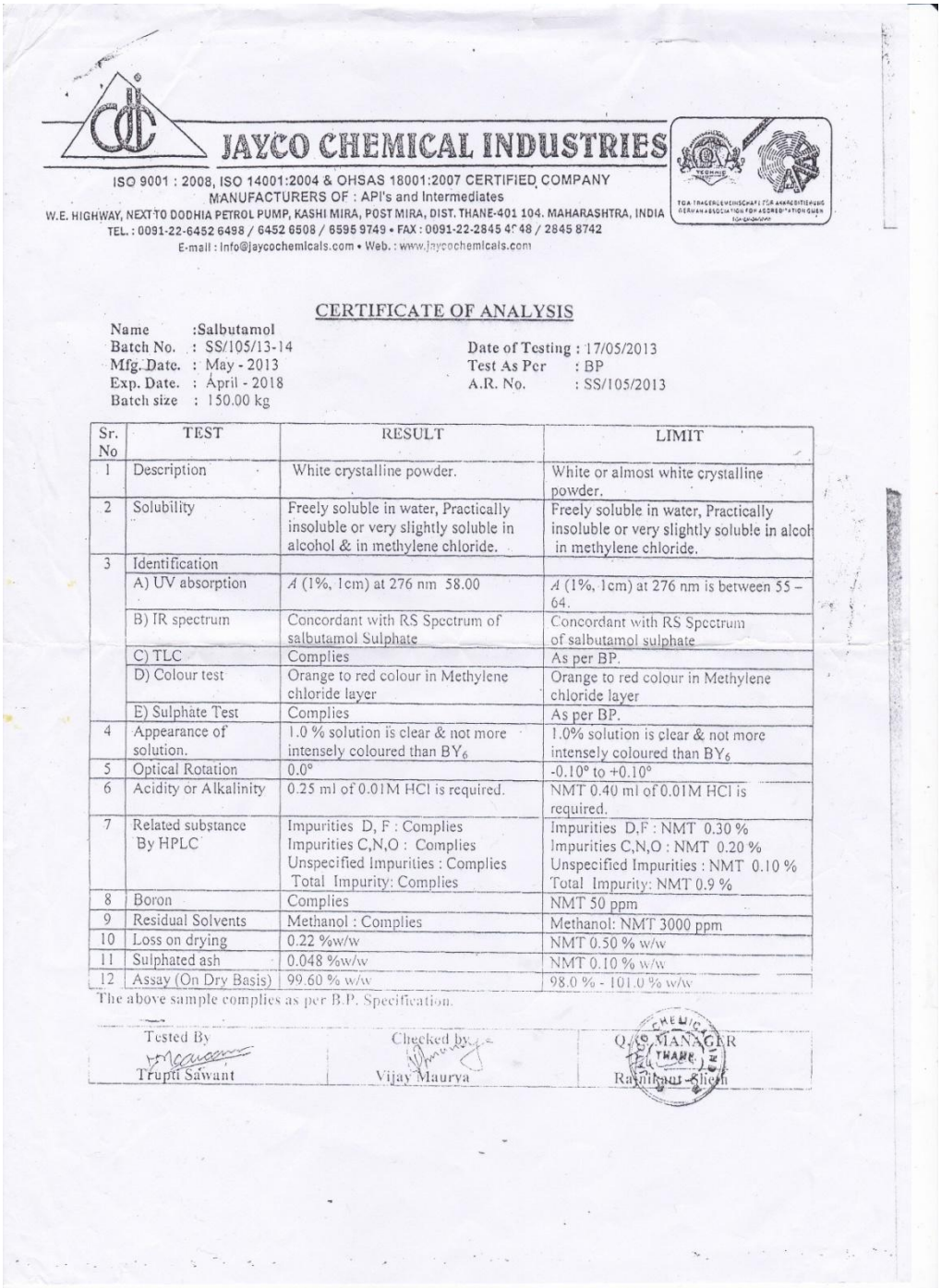
Tranggono, S., Haryadi, Suparmo, A. Murdiati, S. Sudarmadji, K. Rahayu, S. Naruki, dan M. Astuti. 1991. *Bahan Tambahan Makanan (Food Additive).* PAU Pangan dan Gizi UGM, Yogyakarta. Hal 157-162

Triyono, 2012. *Formulasi Tablet Herba Meniran* (*Phyllantus niruri* L.*) dengan Bahan Pengikat Polivinilpirolidon*. [KTI], Surakarta: Fakultas Farmasi, universitas setia budi. Hal 17-19

Voigt, R. 1994. *Buku Pelajaran Teknologi Farmasi*. Yogyakarta : Gadjah Mada University Press. Hlm 165-167, 215-218, 201-210,

Zubaydah, S. 2012. *Formulasi dan optimasi tablet floating salbutamol sulfat menggunakan factorial design.*
(http://etd.ugm.ac.id/index.php?mod=penelitian_detail&sub=PenelitianDetail&act=view&typ=html&buku_id=57535&obyek_id=4) [08 Januari 2013]

Lampiran 1. Sertifikat analisi



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 40 48 / 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

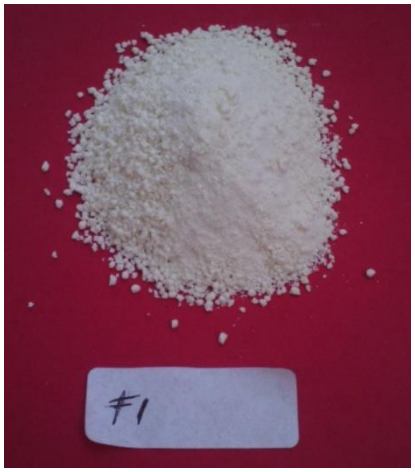
Date of Testing : 17/05/2013
Test As Per : BP
A.R. No. : SS/105/2013

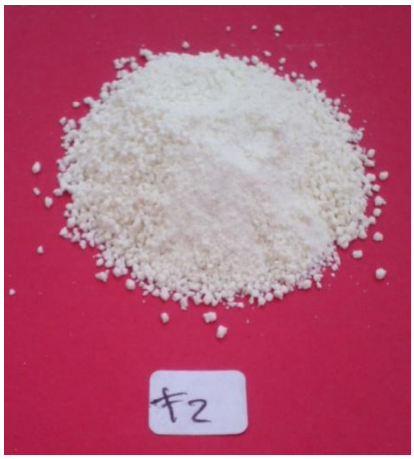
Sr. No	TEST	RESULT	LIMIT
1	Description	White crystalline powder.	White or almost white crystalline powder.
2	Solubility	Freely soluble in water, Practically insoluble or very slightly soluble in alcohol & in methylene chloride.	Freely soluble in water, Practically insoluble or very slightly soluble in alcol 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

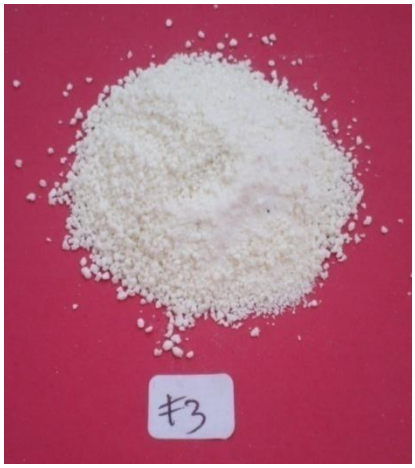
The above sample complies as per B.P. Specification.

Tested By	Checked by	Q.A. MANAGER
Trupti Sawant	Vijay Maurya	Rajnikant Sheth

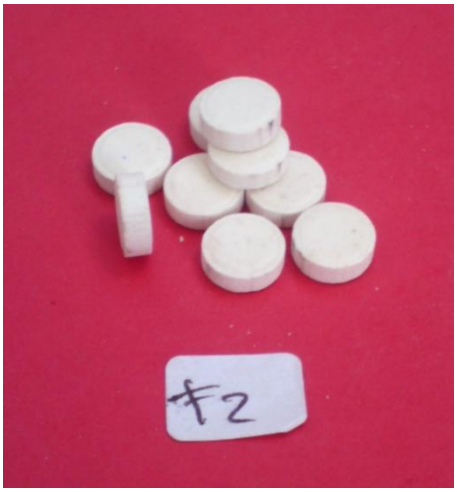
Lampiran 2. Foto granul salbutamol

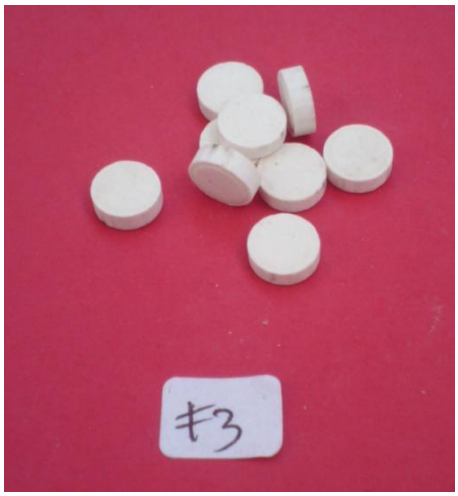






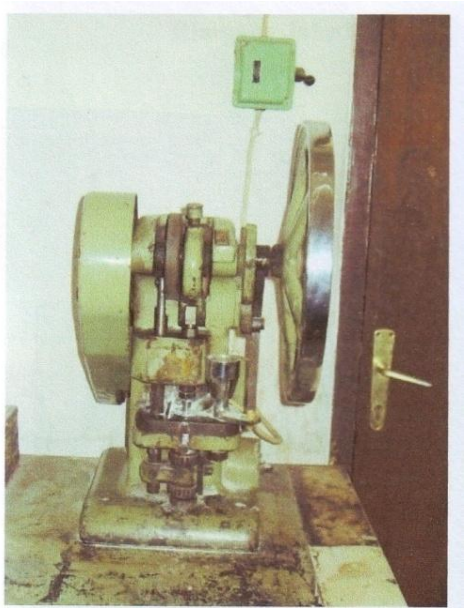
Lampiran 3. foto sediaan tablet salbutamol





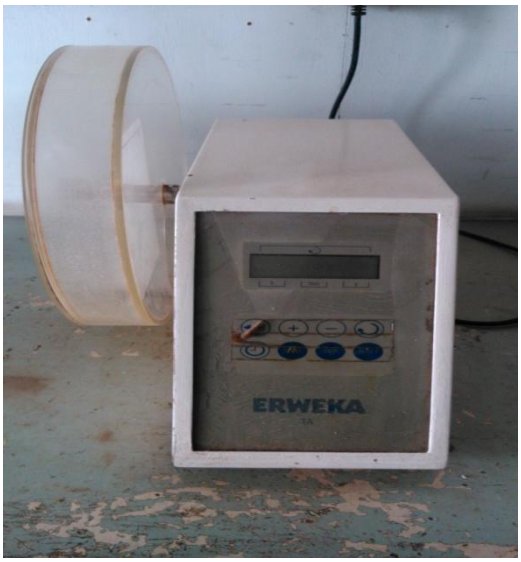
Lampiran 4. Foto alat-alat pengujian sediaan tablet

Moisture Balance



Single punch

Hardness tester



Friability tester

Lampiran 5. Data susut pengeringan

Berat (gram)	Na-CMC : Explotab		
	3% : 5%	4% : 4%	5% : 3%
Berat mula-mula	2,00	2,00	2,00
Berat konstan	1,92	1,91	1,92
LOD %	4,00%	4,50%	4,50%

Contoh perhitungan LOD

$$\% \text{ LOD} = \frac{2{,}00 - 1{,}92}{2{,}00} \times 100\ \%$$

$$= 4{,}00\ \%$$

Lampiran 6. Rancangan formulasi tablet salbutamol

Komposisi tiap tablet	**Formula (mg)**		
	F1 (3% : 5%)	**F2 (4% : 4%)**	**F3 (5% : 3%)**
Salbutamol	4	4	4
Na-CMC	6	8	10
Explotab®	10	8	6
Mg stearat	2	2	2
Laktosa	178	178	178
Berat tablet	200	200	200

Keterangan: F1 : Na-CMC 3% dan Explotab® 5%, F2 : Na-CMC 4% dan Explotab® 4%, F3 : Na-CMC 5% dan Explotab® 3%

Perhitungan bahan pembuatan 100 tablet:

Na-CMC 3% = $\frac{3}{100}$ x 200 = 6 x 100 = 600 mg

Na-CMC 4% = $\frac{4}{100}$ x 200 = 8 x 100 = 800 mg

Na-CMC 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 7. Data waktu alir granul

No.	Waktu Alir Granul (detik) Na-CMC : Explotab		
	3% : 5%	4% : 4%	5% : 3%
1	5.57	6.42	5.35
2	6.42	5.48	5.43
3	5.36	5.52	6.12
4	7.27	7.56	5.23
5	7.54	6.38	7.33
6	6.42	7.28	6.41
7	5.48	5.31	5.18
8	6.31	5.46	6.21
9	6.21	6.45	6.51
10	7.58	5.25	5.26
$\bar{x}$	6,416	6,111	5,903
SD	0,8238	0,8366	0,7243

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
WAKTU ALIR	30	6.1433	.79794	5.18	7.58

One-Sample Kolmogorov-Smirnov Test

		WAKTU ALIR
N		30
Normal Parameters[a,b]	Mean	6.1433
	Std. Deviation	.79794
Most Extreme Differences	Absolute	.197
	Positive	.197
	Negative	-.121
Kolmogorov-Smirnov Z		1.080
Asymp. Sig. (2-tailed)		.194

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

WAKTU ALIR

Levene Statistic	df1	df2	Sig.
.154	2	27	.858

ANOVA

WAKTU ALIR

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1.332	2	.666	1.049	.364
Within Groups	17.133	27	.635		
Total	18.465	29			

Lampiran 8. Data keseragaman bobot tablet salbutamol

N0	keseragaman bobot		
	F1	F2	F3
1	200	200	199
2	202	199	200
3	197	204	202
4	200	202	200
5	201	203	202
6	199	202	203
7	203	199	199
8	198	201	200
9	199	198	201
10	200	205	199
11	199	203	200
12	201	198	201
13	199	200	199
14	200	199	200
15	198	206	204
16	199	200	205
17	200	200	201
18	197	201	198
19	200	199	200
20	198	202	202
$\bar{x}$	3990	4021	4015
SD	3,2403	3,2529	3,2505
CV	1,62	1,61	1,61
Batas atas			
$\bar{x}$ + 7,5%	214.46	216.12	215.80
$\bar{x}$ - 15%	184.54	185.97	185.69
Batas bawah			
$\bar{x}$ + 7,5%	229.43	231.20	230.86
$\bar{x}$ - 15%	169.58	171.12	170.63

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
KESERAGAMAN BOBOT	60	200.43	1.986	197	206

One-Sample Kolmogorov-Smirnov Test

		KESERAGAMAN BOBOT
N		60
Normal Parameters[a,b]	Mean	200.43
	Std. Deviation	1.986
Most Extreme Differences	Absolute	.203
	Positive	.203
	Negative	-.102
Kolmogorov-Smirnov Z		1.573
Asymp. Sig. (2-tailed)		.014

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

KESERAGAMAN BOBOT

Levene Statistic	df1	df2	Sig.
1.913	2	57	.157

ANOVA

KESERAGAMAN BOBOT

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	27.033	2	13.517	3.746	.030
Within Groups	205.700	57	3.609		
Total	232.733	59			

Post Hoc Tests

Multiple Comparisons

KESERAGAMAN BOBOT

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	-1.550*	.601	.043	-3.06	-.04
	FORMULA 3	-1.250	.601	.124	-2.76	.26
FORMULA 2	FORMULA 1	1.550*	.601	.043	.04	3.06
	FORMULA 3	.300	.601	.883	-1.21	1.81
FORMULA 3	FORMULA 1	1.250	.601	.124	-.26	2.76
	FORMULA 2	-.300	.601	.883	-1.81	1.21

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

Homogeneous Subsets

KESERAGAMAN BOBOT

Scheffe[a]

FORMULA TABLET	N	Subset for alpha = 0.05	
		1	2
FORMULA 1	20	199.50	
FORMULA 3	20	200.75	200.75
FORMULA 2	20		201.05
Sig.		.124	.883

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 20.000.

Lampiran 9. Data kekerasan tablet salbutamol

No.	Kekerasan tablet (mg) Na-CMC : Explotab		
	3% : 5%	4% : 4%	5% : 3%
1	8.6	10.4	11.5
2	9.6	9.5	11.5
3	9.5	10.5	10.5
4	9.5	9.6	11.7
5	9.7	10.5	11.3
6	9.8	10.3	11.2
7	8.8	9.5	10.4
8	9.8	10.2	11.1
9	9.7	10.2	11.2
10	9.6	10.6	10.5
$\bar{x}$	94.6	101.3	110.9
SD	0,4168	0,4321	0,465

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
KEKERASAN	30	10.2267	.80126	8.60	11.70

One-Sample Kolmogorov-Smirnov Test

		KEKERASAN
N		30
Normal Parameters[a,b]	Mean	10.2267
	Std. Deviation	.80126
Most Extreme Differences	Absolute	.136
	Positive	.136
	Negative	-.116
Kolmogorov-Smirnov Z		.746
Asymp. Sig. (2-tailed)		.634

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

KEKERASAN

Levene Statistic	df1	df2	Sig.
.229	2	27	.797

ANOVA

KEKERASAN

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	13.425	2	6.712	34.893	.000
Within Groups	5.194	27	.192		
Total	18.619	29			

Post Hoc Tests

Multiple Comparisons

KEKERASAN

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	-.67000*	.19615	.008	-1.1780	-.1620
	FORMULA 3	-1.63000*	.19615	.000	-2.1380	-1.1220
FORMULA 2	FORMULA 1	.67000*	.19615	.008	.1620	1.1780
	FORMULA 3	-.96000*	.19615	.000	-1.4680	-.4520
FORMULA 3	FORMULA 1	1.63000*	.19615	.000	1.1220	2.1380
	FORMULA 2	.96000*	.19615	.000	.4520	1.4680

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

Homogeneous Subsets

KEKERASAN

Scheffe[a]

FORMULA TABLET	N	Subset for alpha = 0.05		
		1	2	3
FORMULA 1	10	9.4600		
FORMULA 2	10		10.1300	
FORMULA 3	10			11.0900
Sig.		1.000	1.000	1.000

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 10.000.

Lampiran 10. Data kerapuhan tablet salbutamol

Berat tablet (g)	Konsentrasi 3% dan 5%			Konsentrasi 4% dan 4%			Konsentrasi 5% dan 3%		
	F1	F2	F3	F1	F2	F3	F1	F2	F3
Sebelum	3.8342	3.8502	3.9764	3.9753	3.9983	4.0862	4.0634	4.1173	4.0821
Sesudah	3.8122	3.8279	3.9539	3.9528	3.9758	4.0641	4.0425	4.0971	4.0625
Kerapuhan %	0,57	0,57	0,56	0,56	0,56	0,54	0,51	0,49	0,48
$\bar{x}$	$\bar{x}$ =0,56			$\bar{x}$ =0,55			$\bar{x}$ =0,49		
	SD =0,007			SD =0,012			SD =0,015		

Contoh perhitungan % kerapuhan tablet = 0,57%

- Berat 20 tablet yang sudah dibebasdebukan = 3,8342 gram
- Berat 20 tablet setelah perlakuan = 3,8122 gram
- % kerapuhan = $\frac{\text{berat awal – berat setelah perlakuan}}{\text{berat awal}}$ X 100 %

$$= \frac{3{,}8342 - 3{,}8122}{3{,}8324} \text{ x } 100\%$$

= 0,57%

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
KERAPUHAN	9	.5414	.03755	.48	.58

One-Sample Kolmogorov-Smirnov Test

		KERAPUHAN
N		9
Normal Parameters[a,b]	Mean	.5414
	Std. Deviation	.03755
Most Extreme Differences	Absolute	.271
	Positive	.157
	Negative	-.271
Kolmogorov-Smirnov Z		.812
Asymp. Sig. (2-tailed)		.526

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

KERAPUHAN

Levene Statistic	df1	df2	Sig.
1.778	2	6	.248

ANOVA

KERAPUHAN

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.010	2	.005	28.082	.001
Within Groups	.001	6	.000		
Total	.011	8			

Post Hoc Tests

Multiple Comparisons

KERAPUHAN

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	.01641	.01100	.388	-.0189	.0517
	FORMULA 3	.07815*	.01100	.001	.0429	.1134
FORMULA 2	FORMULA 1	-.01641	.01100	.388	-.0517	.0189
	FORMULA 3	.06174*	.01100	.004	.0265	.0970
FORMULA 3	FORMULA 1	-.07815*	.01100	.001	-.1134	-.0429
	FORMULA 2	-.06174*	.01100	.004	-.0970	-.0265

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

Homogeneous Subsets

KERAPUHAN

Scheffe[a]

FORMULA TABLET	N	Subset for alpha = 0.05	
		1	2
FORMULA 3	3	.4948	
FORMULA 2	3		.5565
FORMULA 1	3		.5729
Sig.		1.000	.388

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 3.000.

Lampiran 11. Data waktu hancur tablet salbutamol

No.	Waktu hancur (detik) Na-CMC : Explotab		
	F1 3% : 5%	F2 4% : 4%	F3 5% : 3%
1.	10,14	12,13	13,17
2.	10,18	12,12	13,12
3.	10,24	12,15	13,16
4.	10,17	12,23	13,22
5.	10,24	12,18	13,19
6.	10,21	12,2	13,24
SD	0,04	0,042	0,043

NPar Tests

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Waktu hancur	18	11.8494	1.27654	10.14	13.24

One-Sample Kolmogorov-Smirnov Test

		Waktu hancur
N		18
Normal Parameters[a,b]	Mean	11.8494
	Std. Deviation	1.27654
Most Extreme Differences	Absolute	.251
	Positive	.230
	Negative	-.251
Kolmogorov-Smirnov Z		1.063
Asymp. Sig. (2-tailed)		.208

a. Test distribution is Normal.

b. Calculated from data.

Oneway

Test of Homogeneity of Variances

Waktu hancur

Levene Statistic	df1	df2	Sig.
.014	2	15	.986

ANOVA

Waktu hancur

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	27.676	2	13.838	7818.007	.000
Within Groups	.027	15	.002		
Total	27.702	17			

Post Hoc Tests

Multiple Comparisons

Waktu hancur

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	-1.97167*	.02429	.000	-2.0376	-1.9057
	Formula 3	-2.98667*	.02429	.000	-3.0526	-2.9207
Formula 2	Formula 1	1.97167*	.02429	.000	1.9057	2.0376
	Formula 3	-1.01500*	.02429	.000	-1.0809	-.9491
Formula 3	Formula 1	2.98667*	.02429	.000	2.9207	3.0526
	Formula 2	1.01500*	.02429	.000	.9491	1.0809

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

Homogeneous Subsets

Waktu hancur

Scheffe[a]

Formula tablet	N	Subset for alpha = 0.05		
		1	2	3
Formula 1	6	10.1967		
Formula 2	6		12.1683	
Formula 3	6			13.1833
Sig.		1.000	1.000	1.000

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 6.000.