BAB 5
SIMPULAN

5.1. Simpulan

Konsentrasi Tween 80 dan konsentrasi HPMC K4M berpengaruh secara signifikan terhadap kekerasan tablet namun tidak berpengaruh signifikan terhadap kerapuhan, *Hausner Ratio, Carr's Index* dan k disolusi tablet lepas lambat klorfeniramin maleat. Interaksi antara konsentrasi tween 80 dan konsentrasi HPMC K4M juga tidak berpengaruh secara signifikan terhadap sifat fisik tablet dan disolusi tablet klorfeniramin maleat. Formula optimum tablet klorfeniramin maleat dapat diperoleh dengan tween 80 63,5% dalam *liquid medication* dan HPMC K4M 17,5% dari bobot tablet yang akan memberikan prediksi hasil respon kekerasan tablet 10,66 Kp, kerapuhan tablet 0,27%, *Hausner Ratio* 1,24, *Carr's Index* 20,43, dan k disolusi 0,011 mg/menit.

5.2. Alur Penelitian Selanjutnya

Sebaiknya dilakukan penelitian pembuktian beberapa formula optimum terpilih, yang kemudian dibandingkan dengan hasil secara teoritis.

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LAMPIRAN A

HASIL UJI KERAGAMAN BOBOT TABLET LIKUISOLID KLORFENIRAMIN MALEAT

Hasil Uji Keragaman Bobot Tablet Formula A

No	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	**Penyimpangan (%)**	**Bobot Tablet (mg)**	**Penyimpangan (%)**	**Bobot Tablet (mg)**	**Penyimpangan (%)**
1	488,6	4,7080	521,9	2,3976	522,5	2,7431
2	500,5	2,3872	519,2	1,8678	507,4	0,2261
3	507,9	0,9439	503,4	1,2321	515,2	1,3076
4	512,4	0,0663	510,7	0,2001	524,1	3,0577
5	535,4	4,4194	492	3,4688	512,4	0,7571
6	489	4,6300	513,2	0,6906	517,4	1,7402
7	522,6	1,9230	501,4	1,6245	500,9	1,5043
8	525,2	2,4301	510,4	0,1413	490,4	3,5690
9	519,7	1,3574	504,9	0,9378	493,6	2,9397
10	526,1	2,6056	519,7	1,9659	501,6	1,3666
$\bar{X}$	512,74	2,5471	509,68	1,4527	508,55	1,9211
SD		1,6016		1,0331		1,0974

Hasil Uji Keragaman Bobot Tablet Formula B

No	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**
1	545,4	5,2205	519,8	1,2190	491,3	2,4405
2	547,8	5,6835	519,6	1,1800	511,8	1,6303
3	520,8	0,4746	512,2	0,2609	505,8	0,4388
4	487,3	5,9883	519,2	1,1022	492,8	2,1426
5	522	0,7061	507,2	1,2346	514,9	2,2459
6	526,8	1,6321	514,7	0,2259	514,8	2,2260
7	515,8	0,4900	522,5	1,7448	495,7	1,5668
8	464,9	10,3098	512,2	0,2609	504,6	0,2006
9	522,5	0,8026	498,9	2,8508	518,9	3,0402
10	530,1	2,2688	509,1	0,8646	485,3	3,6319
$\bar{X}$	518,34	3,3576	513,54	1,0944	503,59	1,9564
SD		3,3064		0,7991		1,0568

Hasil Uji Keragaman Bobot Tablet Formula C

No	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**
1	511,1	0,8901	514,7	1,0230	495,4	2,1722
2	493,5	4,3030	517,7	0,4461	504,4	0,3949
3	509,9	1,1228	521,8	0,3423	512,1	1,1256
4	527,8	2,3483	519,5	0,1000	513,9	1,4810
5	486,6	5,6410	532,4	2,3807	501,6	0,9479
6	541,1	4,9274	523,8	0,7269	508,7	0,4542
7	517	0,2540	535,6	2,9960	515,8	1,8562
8	535	3,7445	518,5	0,2923	507,8	0,2765
9	499,9	3,0619	518,9	0,2154	494,5	2,3499
10	535	3,7445	497,3	4,3691	509,8	0,6714
$\bar{X}$	515,69	3,0037	520,02	1,2892	506,4	1,1730
SD		1,8086		1,4585		0,7583

Hasil Uji Keragaman Bobot Tablet Formula D

No	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**	**Bobot Tablet (mg)**	**Y (%)**
1	499,2	1,9292	519,6	2,7446	518,8	1,2905
2	517,5	1,6659	502,3	0,6763	512	0,0371
3	518	1,7642	494,3	2,2582	511,3	0,1738
4	507,3	0,3379	512,6	1,3604	507,8	0,8571
5	518,5	1,8624	509,8	0,8068	513	0,1581
6	501,9	1,3988	496,3	1,8627	502,4	1,9114
7	511,1	0,4086	512,9	1,4198	516	0,7439
8	502,9	1,2023	495,6	2,0011	498,5	2,6728
9	504,6	0,8683	503,1	0,5181	519,7	1,4663
10	509,2	0,0354	510,7	0,9847	522,4	1,9934
$\bar{X}$	509,02	1,1473	505,72	1,4633	512,19	1,1304
SD		0,6955		0,7384		0,8914

LAMPIRAN B

HASIL UJI KESERAGAMAN KANDUNGAN TABLET

LIKUISOLID KLORFENIRAMIN MALEAT

Hasil Uji Keragaman Kandungan Tablet Formula A *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,165	11,78	488,6	11,73	100,42
0,17	12,15	500,5	12,01	101,14
0,168	12,00	507,9	12,19	98,44
0,171	12,22	512,4	12,30	99,40
0,178	12,75	535,4	12,85	99,20
0,167	11,93	489	11,74	101,61
0,172	12,30	522,6	12,54	98,06
0,179	12,82	525,2	12,60	101,71
0,174	12,45	519,7	12,47	99,80
0,177	12,67	526,1	12,63	100,36
			X	100,01
			SD	1,26
			KV	1,26

Hasil Uji Keragaman Kandungan Tablet Formula A *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,174	2,45	521,9	12,53	99,38
0,172	12,30	519,2	12,46	98,70
0,17	12,15	503,4	12,08	100,56
0,171	12,22	510,7	12,26	99,73
0,167	11,93	492	11,81	100,99
0,175	12,52	513,2	12,32	101,67
0,166	11,85	501,4	12,03	98,48
0,169	12,07	510,4	12,25	98,57
0,165	11,78	504,9	12,12	97,18
0,172	12,30	519,7	12,47	98,60
			X	99,39
			SD	1,36
			KV	1,36

Hasil Uji Keragaman Kandungan Tablet Formula A *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,172	12,30	522,5	12,54	98,07
0,172	12,30	507,4	12,18	100,99
0,175	12,52	515,2	12,36	101,27
0,176	12,60	524,1	12,58	100,15
0,169	12,07	512,4	12,30	98,19
0,172	12,30	517,4	12,42	99,04
0,171	12,22	500,9	12,02	101,68
0,165	11,78	490,4	11,77	100,06
0,169	12,07	493,6	11,85	101,93
0,17	12,15	501,6	12,04	100,92
			X	100,23
			SD	1,39
			KV	1,39

Hasil Uji Keragaman Kandungan Tablet Formula B *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,181	12,97	545,4	13,09	99,09
0,184	13,19	547,8	13,15	100,36
0,173	12,37	520,8	12,50	98,99
0,164	11,70	487,3	11,70	100,05
0,172	12,30	522	12,53	98,17
0,175	12,52	526,8	12,64	99,04
0,171	12,22	515,8	12,38	98,75
0,156	11,10	464,9	11,16	99,52
0,174	12,45	522,5	12,54	99,26
0,177	12,67	530,1	12,72	99,60
			X	99,28
			SD	0,63
			KV	0,63

Hasil Uji Keragaman Kandungan Tablet Formula B *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,173	12,37	519,8	12,48	99,18
0,175	12,52	519,6	12,47	100,42
0,175	12,52	512,2	12,29	101,87
0,172	12,30	519,2	12,46	98,70
0,169	12,07	507,2	12,17	99,19
0,172	12,30	514,7	12,35	99,56
0,173	12,37	522,5	12,54	98,67
0,175	12,52	512,2	12,29	101,87
0,168	12,00	498,9	11,97	100,22
0,169	12,07	509,1	12,22	98,82
			X	99,85
			SD	1,22
			KV	1,22

Hasil Uji Keragaman Kandungan Tablet Formula B *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,168	12,00	491,3	11,79	101,77
0,169	12,07	511,8	12,28	98,30
0,168	12,00	505,8	12,14	98,85
0,166	11,85	492,8	11,83	100,20
0,172	12,30	514,9	12,36	99,52
0,176	12,60	514,8	12,36	101,96
0,165	11,78	495,7	11,90	98,99
0,171	12,22	504,6	12,11	100,94
0,174	12,45	518,9	12,45	99,95
0,162	11,55	485,3	11,65	99,18
			X	99,97
			SD	1,25
			KV	1,25

Hasil Uji Keragaman Kandungan Tablet Formula C *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,171	12,22	511,1	12,27	99,65
0,164	11,70	493,5	11,84	98,80
0,174	12,45	509,9	12,24	101,72
0,175	12,52	527,8	12,67	98,86
0,161	11,48	486,6	11,68	98,28
0,18	12,90	541,1	12,99	99,30
0,172	12,30	517	12,41	99,12
0,177	12,67	535	12,84	98,69
0,166	11,85	499,9	12,00	98,78
0,181	12,97	535	12,84	101,01
			X	99,42
			SD	1,10
			KV	1,10

Hasil Uji Keragaman Kandungan Tablet Formula C *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,17	12,15	514,7	12,35	98,35
0,171	12,22	517,7	12,42	98,38
0,176	12,60	521,8	12,52	100,59
0,174	12,45	519,5	12,47	99,84
0,177	12,67	532,4	12,78	99,17
0,169	12,07	523,8	12,57	96,05
0,175	12,52	535,6	12,85	97,42
0,169	12,07	518,5	12,44	97,03
0,175	12,52	518,9	12,45	100,55
0,167	11,93	497,3	11,94	99,92
			X	98,73
			SD	1,55
			KV	1,55

Hasil Uji Keragaman Kandungan Tablet Formula C *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,168	12,00	495,4	11,89	100,93
0,172	12,30	504,4	12,11	101,59
0,175	12,52	512,1	12,29	101,89
0,172	12,30	513,9	12,33	99,72
0,168	12,00	501,6	12,04	99,68
0,169	12,07	508,7	12,21	98,90
0,171	12,22	515,8	12,38	98,75
0,168	12,00	507,8	12,19	98,46
0,169	12,07	494,5	11,87	101,74
0,168	12,00	509,8	12,24	98,08
			X	99,97
			SD	1,45
			KV	1,45

Hasil Uji Keragaman Kandungan Tablet Formula D *Batch* I

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,165	11,78	499,2	11,98	98,29
0,172	12,30	517,5	12,42	99,02
0,174	12,45	518	12,43	100,13
0,172	12,30	507,3	12,18	101,01
0,173	12,37	518,5	12,44	99,43
0,167	11,93	501,9	12,05	99,00
0,173	12,37	511,1	12,27	100,87
0,164	11,70	502,9	12,07	96,95
0,172	12,30	504,6	12,11	101,55
0,175	12,52	509,2	12,22	102,47
			X	99,87
			SD	1,65
			KV	1,65

Hasil Uji Keragaman Kandungan Tablet Formula D *Batch* II

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,171	12,22	519,6	12,47	98,02
0,169	12,07	502,3	12,06	100,16
0,163	11,63	494,3	11,86	98,01
0,169	12,07	512,6	12,30	98,15
0,172	12,30	509,8	12,24	100,52
0,167	11,93	496,3	11,91	100,12
0,168	12,00	512,9	12,31	97,48
0,165	11,78	495,6	11,89	99,01
0,172	12,30	503,1	12,07	101,86
0,169	12,07	510,7	12,26	98,51
			X	99,18
			SD	1,41
			KV	1,41

Hasil Uji Keragaman Kandungan Tablet Formula D *Batch* III

Abs	C sampel	W sampel	C teoritis	Kadar (persen)
0,177	12,67	518,8	12,45	101,77
0,172	12,30	512	12,29	100,09
0,172	12,30	511,3	12,27	100,22
0,167	11,93	507,8	12,19	97,85
0,169	12,07	513	12,31	98,07
0,172	12,30	502,4	12,06	102,00
0,171	12,22	516	12,38	98,71
0,165	11,78	498,5	11,96	98,43
0,173	12,37	519,7	12,47	99,20
0,177	12,67	522,4	12,54	101,07
			X	99,74
			SD	1,52
			KV	1,52

LAMPIRAN C
HASIL PENETAPAN KADAR TABLET LIKUISOLID KLORFENIRAMIN MALEAT

Formula	Repli-kasi	Absor-bansi	Csampel (µg/ml)	Cteoritis (µg/ml)	Kadar (%)	$\bar{x}$ ±SD
A	1	0,169	12,0746	12,0288	100,38	99,90 ± 0,55
	2	0,168	12,0000	12,0840	99,30	
	3	0,169	12,0746	12,0720	100,02	
B	1	0,167	11,9254	11,9808	99,54	100,37 ± 0,73
	2	0,169	12,0746	11,9904	100,70	
	3	0,170	12,1493	12,0432	100,88	
C	1	0,169	12,0746	12,0456	100,24	100,61 ± 0,95
	2	0,172	12,2985	12,0936	101,69	
	3	0,169	12,0746	12,0864	99,90	
D	1	0,171	12,2239	12,0576	101,38	99,97 ± 1,22
	2	0,167	11,9254	12,0216	99,20	
	3	0,167	11,9254	12,0048	99,34	

LAMPIRAN D

HASIL KLORFENIRAMIN MALEAT TERLARUT DALAM TWEEN 80 SELAMA 24 JAM

W sampel (gram)	Abs.	Cs (µg/ml)	Rata-rata (µg/ml)
10,0020	0,110	7,67	
10,0013	0,121	8,49	8,19
10,0080	0,120	8,42	

LAMPIRAN E
CONTOH PERHITUNGAN

Contoh perhitungan Carr's Indexdan *Hausner Ratio*:

Formula A :

Berat gelas = 125,8641 g (W1)

Berat gelas + granul = 153,9399 g (W2)

V1 = 100 ml

V2 = 83 ml

Bj nyata $= \frac{(W_2 - W_1)}{V_1} = \frac{(153,9399 - 125,8641)}{100} = 0,280758$

Bj mampat $= \frac{(W_2 - W_1)}{V_2} = \frac{(153,9399 - 125,8641)}{83} =$ 0,33826

% kompresibilitas $= \left(1 - \frac{Bj.nyata}{Bj\ mampat}\right) x100\% = 17\%$

Formula A:

HR $= \frac{Bj\ mampat}{Bj\ nyata} = 1,20$

Contoh perhitungan akurasi & presisi:

%	Bahan aktif (mg)	Matriks (mg)	Akuades Ad	Pipet	Akuades Ad	Konsentrasi (ppm)
100	12	488	100	0,8	10	9,6

Absorbansi = 0,137 → y = 0,0134x + 0,0072

Konsentrasi sebenarnya = 9,69 ppm

Konsentrasi teoritis = 9,63 ppm

% perolehan kembali = (konsentrasi sebenarnya / konsentrasi teoritis) x 100%

= (9,69 /9,63) x 100%

= 100,57 %

Untuk menghitung % KV = $\frac{SD}{\bar{X}} x100\%$

= $\frac{1,21}{100,45} x\ 100\%$

= 1,21 %

Contoh perhitungan % obat terlepas:

% obat terlepas = $\frac{Wt}{\frac{PK}{100} \times dosis} \times 100\%$

Formula A replikasi 1 pada t = 30 menit

% obat terlepas = $\frac{3,6806}{\frac{98,1147}{100} \times 12} \times 100\% = 31,2610\%$

Contoh Perhitungan Jumlah Klorfeniramin Maleat terlarut dalam Tween 80:

Replikasi I:

W sampel: 10,002 gram

Absorbansi = 0,11 → y = 0,0134x + 0,0072

Konsentrasi sebenarnya = 7,67 ppm

W tween: 25 ml

Konsentrasi teoritis = (W sampel/W tween) x 1000

= (10,002/25) x 1000

= 400,08 ppm

Pipet 25µl ad 50 ml= (400,08 x 25) / 50 = 200,04

Kadar = (7,67 / 200,04)* 100% = 3,84

Perbandingan = 1:26

LAMPIRAN F

HASIL UJI F KURVA BAKU

REPLIKASI I

KONSENTRASI	ABSORBANSI	X^2	Y^2	XY
3,015	0,046	9,0902	0,0021	0,1387
5,025	0,077	25,2506	0,0059	0,3869
7,035	0,102	49,4912	0,0104	0,7176
9,045	0,128	81,8120	0,0164	1,1578
11,055	0,155	122,2130	0,0240	1,7135
13,065	0,183	170,6942	0,0335	2,3909

REPLIKASI II

KONSENTRASI	ABSORBANSI	X^2	Y^2	XY
3,015	0,047	9,0902	0,0022	0,1417
5,025	0,072	25,2506	0,0052	0,3618
7,035	0,106	49,4912	0,0112	0,7457
9,045	0,136	81,8120	0,0185	1,2301
11,055	0,161	122,2130	0,0259	1,7799
13,065	0,193	170,6942	0,0372	2,5215

REPLIKASI III

KONSENTRASI	ABSORBANSI	X^2	Y^2	XY
3	0,046	9,0721	0,0021	0,1386
5,02	0,074	25,2004	0,0055	0,3715
7,028	0,104	49,3928	0,0108	0,7309
9,036	0,126	81,6493	0,0159	1,1385
11,044	0,158	121,9699	0,0250	1,7450
13,052	0,185	170,3547	0,0342	2,4146

	ΣX^2	ΣXY	ΣY^2	N	Residual SS	RDF
Replikasi I	458,5514	6,5054	0,0923	6	$5,6848.10^{-5}$	4
Replikasi II	458,5514	6,7807	0,1003	6	$2,6256. 10^{-5}$	4
Replikasi III	457,6393	6,5391	0,0935	6	$3,8707. 10^{-5}$	4
Pooled regression					$1,22. 10^{-4}$	12
Common regression	1374,7420	19,8252	0,2861		$2,17.10^{-4}$	11

F hitung < F tabel $_{0,05\,(2,9)}$ = 3,1096 < 8,74

Karena F hitung lebih kecil dari F tabel maka tidak ada perbedaan bermakna antar persamaan regresi.

LAMPIRAN H

SERTIFIKAT ANALISIS KLORFENIRAMIN MALEAT

PT Chemco Corp.
JAKARTA

SUPRIYA LIFESCIENCE LTD.
(Formerly known as **Supriya Chemicals**)

QCA-F-02
Rev. No. 01

CERTIFICATE OF ANALYSIS

Name	:	**Chlorpheniramine Maleate USP**			
Manufacture	:	**Supriya Lifescience Ltd.**	A.R.Number	:	SLL/QC/FP/11/0074
Batch No.	:	SLL/C/0111016	Drug License No.	:	KD-129
Batch Size	:	1000.0 kgs	Date of Sampling	:	29/01/2011
Date of Manufacturing	:	Jan-2011	Date of Release	:	30/01/2011
Date of Expiry	:	Dec-2015	Sampled By	:	SUN
Quantity Sampled	:	60 gms			

Tests	Specification & Limits	Results
Description	White, odourless, crystalline powder	White, odourless,Crystalline powder
Solublity	Freely soluble in water, soluble in alcohol ,and in chloroform ,slightly soluble in ether , and in benzene	Freely soluble in water, soluble in alcohol, and in chloroform, slightly soluble in ether, and in benzene
Identification: **IR Absorption**	The infra red absorption spectrum should be concordant with the reference spectrum of chlorpheniramine maleate	The infra red absorption spectrum is concordant with the reference spectrum of chlorpheniramine maleate
Melting Range	130°C to 135°C	133-134°C
Loss on Drying	Not more than 0.5%	0.22%
Residue on Ignition	Not more than 0.2%	0.05%
Related Compounds	Total impurity not more than 2.0%	0.52%
Assay (on dried basis)	NLT 98.0% and NMT 100.5%	99.72%
Residual Solvents		
Isopropanol	Not more than 5000ppm	438ppm
O-xylene	Not more than 2170ppm	Not detected
Methanol	Not more than 3000ppm	Not detected

REMARKS: Chlorpheniramine maleate complies / ~~does not comply~~ with respect to above mentioned test as per USP 32 Specification

Analysed By	Checked By	Quality Control Manager

Corporate office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai – 400 063. Maharashtra, India.
Tel: +91 22 40332727 / 66942507 Fax : +91 22 26860011
E-mail: supriya@supriyalifescience.com Website: www.supriyalifescience.com

Factory : A 5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal.- Khed, Dist.- Ratnagiri, 415 722, Maharashtra, India.
Tel: +91 2356 272299 Fax : +91 2356 272178
E-mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE

SERTIFIKAT ANALISIS Avicel PH-102

AsahiKASEI
ASAHI KASEI CHEMICALS

1-105 Kanda Jinbocho, Chiyoda-ku, TOKYO 101-8101, JAPAN
TEL +81-(0)3-3296-3361 FAX +81-(0)3-3296-3467
Manufacturing site: 304, Mizushiri-machi, Nobeoka-city, Miyazaki 882-0015, Japan

Date: 26-SEP-2012
Issued by manufacturer

3037/BB/XI/12
3051/BB/XI/12

YOUR NO.: B7ME-12-5298-0089

CERTIFICATE OF ANALYSIS

Compendial name: Microcrystalline Cellulose, NF, Ph. Eur., JP

Trade name : CEOLUS®

Grade : PH-102 **Lot No. 2291 (320bags)**

Manufacturing Date: 05-SEP-2012
Re-evaluation Date: 05-SEP-2015

Organic Solvent: not used in our process

Compendial Standards	Specifications	Lot Analysis
Description	Passes	Passes
Identification	Passes	Passes
Degree of polymerization	100 - 300	Passes
Loss on drying (%)	2.0 - 5.0	4.0
Water-soluble substances (mg)	NMT 12.5	6.2
Ether-soluble substances (mg)	NMT 5.0	0.6
Conductivity (μS/cm)	NMT 75	24
Heavy metals (ppm)	NMT 10	NMT 10
Solubility	Passes	Passes
Residue on ignition (%)	NMT 0.1	0.00
Bulk density (g/cm^3)	0.28 - 0.33	0.303
pH	5.0 - 7.5	6.2
Total aerobic microbial count (cfu/g)	NMT 1000	Passes
Total combined molds and yeasts count (cfu/g)	NMT 100	Passes
Escherichia coli	None Present	None Present
Salmonella species	None Present	None Present
Pseudomonas Aeruginosa	None Present	None Present
Staphylococcus Aureus	None Present	None Present
ASAHI Standards		
Particle size, wt. % >250μm (60 mesh)	LT 8.0	0.8
Particle size, wt. % >150μm (100 mesh)	20 - 40	33

NMT –Not More Than; LT –Less Than
We certify that the product complies with the standards of the NF, Ph. Eur., JP.
Storage conditions: Store at ambient conditions. Keep containers sealed; material is hygroscopic.

P.T. WARIS
JAKARTA

Re-evaluation Date: Three years after manufacturing, if stored as recommended.
Asahi Kasei Chemicals recommends that the customer's quality control unit may re-evaluate the quality of this material at the given time e.g. for loss on drying and extend the shelf life of this lot on its own responsibility.

Shuji OMISHI
Manager
Quality Assurance Section
CEOLUS Production Department

Donda Siregar, S. Farm., Apt.
SP. No. KP. 01.03.1.3.0661
Apoteker Penanggung Jawab

LAMPIRAN I

TABEL DISTRIBUSI F UNTUK 5% DAN 1%

Baris atas untuk taraf signifikan 5%
Baris bawah untuk taraf signifikan 1%

V_2 = dk penyebut	V_1 = dk pembilang																						
	1	2	3	4	5	6	7	8	9	10	11	12	14	16	20	24	30	40	50	75	100	200	500	∞
1	161	200	216	225	230	234	237	239	241	242	243	244	245	246	248	249	250	251	252	253	253	254	254	254
	4052	4999	5403	5625	5764	5859	5928	5961	6022	6056	6082	6106	6142	61,69	6208	6234	6258	6286	6302	6323	6334	6352	6361	6366
2	18,51	19,00	19,16	19,25	19,30	19,33	19,36	19,37	19,38	19,39	19,40	19,41	19,42	19,43	19,44	19,45	19,46	19,47	19,47	19,48	19,49	19,49	19,50	19,50
	98,49	99,01	99,17	99,25	99,30	99,33	99,34	99,36	97,38	99,40	99,41	99,42	99,43	99,44	99,45	99,46	99,47	99,48	99,48	99,49	99,49	99,49	99,50	99,50
3	10,13	9,55	9,28	9,12	9,01	8,94	8,88	8,84	8,81	8,78	8,76	8,74	8,71	8,69	8,66	8,64	8,62	8,60	8,58	8,57	8,56	8,54	8,54	8,53
	34,12	30,81	29,46	28,71	28,24	27,91	27,67	27,49	27,34	27,23	27,13	27,05	26,92	26,83	26,69	26,60	26,50	26,41	26,30	26,27	26,23	26,18	26,14	26,12
4	7,71	6,94	6,59	6,39	6,26	6,16	6,09	6,04	6,00	5,96	5,93	5,91	5,87	5,84	5,80	5,77	5,74	5,71	5,70	5,68	5,66	5,65	5,64	5,53
	21,20	18,00	16,69	15,98	15,52	15,21	14,98	14,80	14,66	14,54	14,45	14,37	14,24	14,15	14,02	13,93	13,83	13,74	13,69	13,61	13,57	13,52	13,48	13,46
5	6,61	5,79	5,41	5,19	5,05	4,95	4,88	4,82	4,78	4,74	4,70	4,68	4,64	4,60	4,56	4,53	4,50	4,46	4,44	4,42	4,40	4,38	4,37	4,36
	16,26	13,27	12,06	11,39	10,97	10,67	10,45	10,27	10,15	10,05	9,96	9,89	9,77	9,68	9,55	9,47	9,38	9,29	9,24	9,17	9,13	9,07	9,04	9,02
6	5,99	5,14	4,76	4,53	4,39	4,28	4,21	4,15	4,10	4,06	4,03	4,00	3,96	3,92	3,87	3,84	3,81	3,77	3,75	3,72	3,71	3,69	3,68	3,67
	13,74	10,92	9,78	9,15	8,75	8,47	8,26	8,10	7,98	7,87	7,79	7,72	7,60	7,52	7,39	7,31	7,23	7,14	7,09	7,02	6,99	6,94	6,90	6,88
7	5,59	4,74	4,35	4,12	3,97	3,87	3,79	3,73	3,68	3,63	3,60	3,57	3,52	3,49	3,44	3,41	3,38	3,34	3,32	3,29	3,28	3,25	3,24	3,23
	12,25	9,55	8,45	7,85	7,46	7,19	7,00	6,84	6,71	6,62	6,54	6,47	6,35	6,27	6,15	6,07	5,98	5,90	5,85	5,78	5,75	5,70	5,67	5,65
8	5,32	4,46	4,07	3,84	3,69	3,58	3,50	3,44	3,39	3,34	3,31	3,28	3,23	3,20	3,15	3,12	3,08	3,05	3,03	3,00	2,98	2,96	2,94	2,93
	11,26	8,65	7,59	7,01	6,63	6,37	6,19	6,03	5,91	5,82	5,74	5,67	5,56	5,48	5,36	5,28	5,20	5,11	5,06	5,00	4,96	4,91	4,88	4,86
9	5,12	4,26	3,86	3,63	3,48	3,37	3,29	3,23	3,18	3,13	3,10	3,07	3,02	2,98	2,93	2,90	2,86	2,82	2,80	2,77	2,76	2,73	2,72	2,71
	10,56	8,02	6,99	6,42	6,06	5,80	5,62	5,47	5,35	5,26	5,18	5,11	5,00	4,92	4,80	4,73	4,61	4,56	4,51	4,45	4,41	4,36	4,33	4,34

LAMPIRAN J
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

LAMPIRAN K

HASIL UJI ANAVA *HAUSNER RATIO* KLORFENIRAMIN MALEAT DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response 2 Hausner ratio

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
Model	3.333E-005	3	1.111E-005	0.33	
A-konsentrasi tween	3.333E-005	1	3.333E-005	1.00	
B-konsentrasi hpmc	0.000	1	0.000	0.000	
AB	0.000	1	0.000	0.000	
Pure Error	2.667E-004	8	3.333E-005		
Cor Total	3.000E-004	11			

The "Model F-value" of 0.33 implies the model is not significant relative to the noise. There is a
80.18 % 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 there are no 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.	5.774E-003	R-Squared	0.1111
Mean	1.25	Adj R-Squared	-0.2222
C.V. %	0.46	Pred R-Squared	-1.0000
PRESS	6.000E-004	Adeq Precision	1.000

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your
response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 1.00 indicates an inadequate
signal and we should not use this model to navigate the design space.

Factor	Coefficient Estimate	df	95% CI Error	95% CI Low
Intercept	1.25	1	1.667E-003	1.24

A-konsentrasi tween	1.667E-003	1	1.667E-003	-2.177E-003
B-konsentrasi hpmc	0.000	1	1.667E-003	-3.843E-003
AB	0.000	1	1.667E-003	-3.843E-003

Final Equation in Terms of Coded Factors:

Hausner ratio =
+1.25
+1.667E-003 * A
+0.000 * B
+0.000 * A * B

Final Equation in Terms of Actual Factors:

Hausner ratio =
+1.24500
+1.66667E-003 * konsentrasi tween
-1.26445E-016 * konsentrasi hpmc
+1.26445E-016 * konsentrasi tween * konsentrasi hpmc

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.

HASIL UJI ANAVA CARR'S INDEX KLORFENIRAMIN MALEAT DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response 1 Carrs index

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
Model	0.25	3	0.083	0.25	
A-konsentrasi tween	0.040	1	0.040	0.12	
B-konsentrasi hpmc	0.21	1	0.21	0.62	
AB	4.408E-003	1	4.408E-003	0.013	
Pure Error	2.67	8	0.33		
Cor Total	2.92	11			

The "Model F-value" of 0.25 implies the model is not significant relative to the noise. There is a
85.97 % 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 there are no 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.	0.58	R-Squared	0.0855
Mean	20.43	Adj R-Squared	-0.2574
C.V. %	2.83	Pred R-Squared	-1.0576
PRESS	6.00	Adeq Precision	1.130

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your
response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 1.13 indicates an inadequate
signal and we should not use this model to navigate the design space.

Factor	Coefficient Estimate	df	95% CI Error	95% CI Low
Intercept	20.43	1	0.17	20.04
A-konsentrasi tween	0.057	1	0.17	-0.33

B-konsentrasi hpmc	0.13	1	0.17	-0.25
AB	0.019	1	0.17	-0.37

Final Equation in Terms of Coded Factors:

Carrs index =
+20.43
+0.057 * A
+0.13 * B
+0.019 * A * B

Final Equation in Terms of Actual Factors:

Carrs index =
+20.42583
+0.057500 * konsentrasi tween
+0.13083 * konsentrasi hpmc
+0.019167 * konsentrasi tween * konsentrasi hpmc

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.

HASIL UJI ANAVA KERAPUHAN TABLET KLORFENIRAMIN MALEAT DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response 4 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
Model	0.27	3	0.091	1.08	
A-konsentrasi tween	0.15	1	0.15	1.75	
B-konsentrasi hpmc	0.070	1	0.070	0.83	
AB	0.057	1	0.057	0.67	
Pure Error	0.68	8	0.085		
Cor Total	0.95	11			

The "Model F-value" of 1.08 implies the model is not significant relative to the noise. There is a
41.03 % 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 there are no 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.	0.29	R-Squared	0.2886
Mean	0.23	Adj R-Squared	0.0218
C.V. %	125.87	Pred R-Squared	-0.6006
PRESS	1.52	Adeq Precision	2.232

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your
response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 2.23 indicates an inadequate
signal and we should not use this model to navigate the design space.

Factor	Coefficient Estimate	df	95% CI Error	95% CI Low
Intercept	0.23	1	0.084	0.037
A-konsentrasi tween	0.11	1	0.084	-0.083

B-konsentrasi hpmc	0.076	1	0.084	-0.12
AB	0.069	1	0.084	-0.12

Final Equation in Terms of Coded Factors:

kerapuhan =
+0.23
+0.11 * A
+0.076 * B
+0.069 * A * B

Final Equation in Terms of Actual Factors:

kerapuhan =
+0.23097
+0.11098 * konsentrasi tween
+0.076300 * konsentrasi hpmc
+0.068683 * konsentrasi tween * konsentrasi hpmc

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.

HASIL UJI ANAVA KEKERASAN TABLET KLORFENIRAMIN MALEAT DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response 3 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
Model	74.53	3	24.84	11.14	
A-konsentrasi tween	53.30	1	53.30	23.91	
B-konsentrasi hpmc	17.55	1	17.55	7.87	
AB	3.69	1	3.69	1.65	
Pure Error	17.83	8	2.23		
Cor Total	92.36	11			

The Model F-value of 11.14 implies the model is significant. There is only a 0.31% 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 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.	1.49	R-Squared	0.8069
Mean	11.64	Adj R-Squared	0.7345
C.V. %	12.83	Pred R-Squared	0.5656
PRESS	40.13	Adeq Precision	7.695

The "Pred R-Squared" of 0.5656 is in reasonable agreement with the "Adj R-Squared" of 0.7345.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your
ratio of 7.695 indicates an adequate signal. This model can be used to navigate the design space.

Coefficient Factor	Standard Estimate	95% CI df	95% CI Error	Low
Intercept	11.64	1	0.43	10.64
A-konsentrasi tween	-2.11	1	0.43	-3.10

B-konsentrasi hpmc	-1.21	1	0.43	-2.20
AB	-0.55	1	0.43	-1.55

Final Equation in Terms of Coded Factors:

kekerasan =
+11.64
-2.11 * A
-1.21 * B
-0.55 * A * B

Final Equation in Terms of Actual Factors:

kekerasan =
+11.63750
-2.10750 * konsentrasi tween
-1.20917 * konsentrasi hpmc
-0.55417 * konsentrasi tween * konsentrasi hpmc

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.

HASIL UJI ANAVA KONSTANTA LAJU DISOLUSI KLORFENIRAMIN MALEAT DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response	5	k 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
Model	2.573E-003	3	8.578E-004	0.95	
A-konsentrasi tween	1.066E-003	1	1.066E-003	1.18	
B-konsentrasi hpmc	7.410E-004	1	7.410E-004	0.82	
AB	7.664E-004	1	7.664E-004	0.85	
Pure Error	7.215E-003	8	9.018E-004		
Cor Total	9.788E-003	11			

The "Model F-value" of 0.95 implies the model is not significant relative to the noise. There is a
46.07 % 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 there are no 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.	0.030	R-Squared	0.2629
Mean	0.018	Adj R-Squared	-0.0135
C.V. %	163.28	Pred R-Squared	-0.6584
PRESS	0.016	Adeq Precision	2.009

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your
response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 2.01 indicates an inadequate
signal and we should not use this model to navigate the design space.

Factor	Coefficient Estimate	df	95% CI Error	95% CI Low
Intercept	0.018	1	8.669E-003	-1.599E-003
A-konsentrasi tween	-9.425E-003	1	8.669E-003	-0.029

B-konsentrasi hpmc	7.858E-003	1	8.669E-003	-0.012
AB	-7.992E-003	1	8.669E-003	-0.028

Final Equation in Terms of Coded Factors:

k disolusi =
+0.018
-9.425E-003 * A
+7.858E-003 * B
-7.992E-003 * A * B

Final Equation in Terms of Actual Factors:

k disolusi =
+0.018392
-9.42500E-003 * konsentrasi tween
+7.85833E-003 * konsentrasi hpmc
-7.99167E-003 * konsentrasi tween * konsentrasi hpmc

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