BAB 5

SIMPULAN DAN ALUR PENELITIAN SELANJUTNYA

5.1 Simpulan

Pengaruh matriks HPMC dalam sediaan *patch* transdermal terhadap karakteristik penetrasi ternyata dapat meningkatkan penetrasi natrium diklofenak lebih besar daripada pengaruh polimer Etil selulosa dalam sediaan *patch* transdermal natrium diklofenak terhadap karakteristik penetrasi natrium diklofenak, ini dikarenakan polimer HPMC bersifat hidrofilik.

Dari hasil analisis berdasarkan *design expert*, didapatkan formula optimum ditinjau dari pelepasan, penetrasi dan ketahanan lipat patch natrium diklofenak, yaitu pada kosentrasi HPMC 300 mg dan etil selulosa 500 mg.

5.2 Alur Penelitian Selanjutnya

Dari hasil kesimpulan penelitian kali ini, maka saran untuk penelitian selanjutnya adalah sediaan *patch* natrium diklofenak dengan sistem matrik yang menggunakan 2 macam polimer sebagai pengontrol pelepasan natrium diklofenak dapat dimodifikasi menjadi sistem reservoir, dengan begitu kecepatan pelepasan dari bahan aktif natrium diklofenak dapat lebih dikendalikan dan sediaan *patch* transdermal yang telah dibuat di uji secara *in vivo* pada kulit hewan.

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PERHITUNGAN *MOISTURE CONTENT (MC)*

Formula -1			
W (g)	Wp (g)	Wa (g)	MC (%)
0,0932	0,0786	0,0146	15,67
0,0798	0,0664	0,0134	16,79
0,0904	0,0751	0,0153	16,92
		Rata - rata	16,46 ± 0,69

Formula a			
W (g)	Wp (g)	Wa (g)	MC (%)
0,1013	0,0839	0,0174	17,18
0,0940	0,0783	0,0157	16,74
0,0877	0,0737	0,0140	16,00
		Rata - rata	16,64 ± 0,59

Formula b			
W (g)	Wp (g)	Wa (g)	MC (%)
0,0979	0,0794	0,0185	18,93
0,0928	0,0774	0,0154	16,59
0,0859	0,0713	0,0146	16,96
		Rata - rata	17,49 ± 1,26

Formula ab			
W (g)	Wp (g)	Wa (g)	MC (%)
0,0930	0,0755	0,0175	18,85
0,0785	0,0650	0,0135	17,20
0,0927	0,0776	0,0151	16,33
		Rata - rata	17,46 ± 1,28

Keterangan :

W = berat mula mula

Wp = berat kering (setelah dimasukkan desikator selama 24 jam)

Wa = selisih antara W dan Wp

MC = $\frac{Wa}{Wp}$ x 100

HASIL UJI ANAVA *MOISTURE CONTENT (MC)*

Descriptives

MC

	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
f_1	3	16.46	.68724	.39678	14.7528	18.1672	15.67	16.92
f_2	3	16.64	.59632	.34429	15.1587	18.1213	16.00	17.18
f_3	3	17.49	1.25787	.72623	14.3686	20.6181	16.59	18.93
f_4	3	17.46	1.27996	.73899	14.2804	20.6396	16.33	18.85
Total	12	17.01	.98734	.28502	16.3860	17.6407	15.67	18.93

ANOVA

MC

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	2.626	3	.875	.865	.498
Within Groups	8.097	8	1.012		
Total	10.723	11			

Multiple Comparisons

Dependent Variable:MC

	(I) f	(J) f	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	Upper Bound
Tukey HSD	f_1	f_2	-.18000	.82142	.996	-2.8105	2.4505
		f_3	-1.03333	.82142	.611	-3.6638	1.5972
		f_4	-1.00000	.82142	.634	-3.6305	1.6305
	f_2	f_1	.18000	.82142	.996	-2.4505	2.8105
		f_3	-.85333	.82142	.733	-3.4838	1.7772
		f_4	-.82000	.82142	.755	-3.4505	1.8105
	f_3	f_1	1.03333	.82142	.611	-1.5972	3.6638
		f_2	.85333	.82142	.733	-1.7772	3.4838
		f_4	.03333	.82142	1.00	-2.5972	2.6638
	f_4	f_1	1.00000	.82142	.634	-1.6305	3.6305
		f_2	.82000	.82142	.755	-1.8105	3.4505
		f_3	-.03333	.82142	1.00	-2.6638	2.5972
LSD	f_1	f_2	-.18000	.82142	.832	-2.0742	1.7142
		f_3	-1.03333	.82142	.244	-2.9275	.8609
		f_4	-1.00000	.82142	.258	-2.8942	.8942
	f_2	f_1	.18000	.82142	.832	-1.7142	2.0742
		f_3	-.85333	.82142	.329	-2.7475	1.0409

	f_4	-.82000	.82142	.347	-2.7142	1.0742
f_3	f_1	1.03333	.82142	.244	-.8609	2.9275
	f_2	.85333	.82142	.329	-1.0409	2.7475
	f_4	.03333	.82142	.969	-1.8609	1.9275
f_4	f_1	1.00000	.82142	.258	-.8942	2.8942
	f_2	.82000	.82142	.347	-1.0742	2.7142
	f_3	-.03333	.82142	.969	-1.9275	1.8609

MC

			Subset for alpha = 0.05
	formula	N	1
Tukey HSD[a]	formula_1	3	16.4600
	formula_2	3	16.6400
	formula_4	3	17.4600
	formula_3	3	17.4933
	Sig.		.611

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 3,000.

LAMPIRAN C

DATA KURVA BAKU AQUADEST DENGAN TIGA KALI REPLIKASI

Pengujian hari 1

Konsentrasi (µg/ml)	Absorbansi
2,008	0,052
8,032	0,203
14,056	0,344
20,080	0,498
26,104	0,649
a	0,0017
b	0,0247
r hitung	0,9998

Pengujian hari 2

Konsentrasi (µg/ml)	Absorbansi
2,024	0,063
8,096	0,269
14,168	0,457
20,240	0,555
26,312	0,703
a	0,0440
b	0,0258
r hitung	0,9834

Pengujian hari 3

Konsentrasi (µg/ml)	Absorbansi
2,012	0,070
8,048	0,222
14,084	0,390
20,120	0,534
26,156	0,670
a	0,0233
b	0,0251
r hitung	0,9988

LAMPIRAN D

HASIL UJI ANAVA DATA KURVA BAKU AQUADEST

	N	Mean	SD	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Rep_1	5	.34920	.235	.105	.05685	.64155	.052	.649
Rep_2	5	.40940	.249	.111	.09937	.71943	.063	.703
Rep_3	5	.37720	.239239	.106991	.08015	.67425	.070	.670
Total	15	.37860	.225062	.058111	.25397	.50323	.052	.703

ANOVA

VAR00001

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	.009	2	.005	.078	.926
Within Groups	.700	12	.058		
Total	.709	14			

Multiple Comparisons

Dependent Variable:VAR00001

	Rep	(J) Rep	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Tukey HSD	Rep_1	Rep_2	-.060200	.152759	.919	-.46774	.34734
		Rep_3	-.028000	.152759	.982	-.43554	.37954
	Rep_2	Rep_1	.060200	.152759	.919	-.34734	.46774
		Repi_3	.032200	.152759	.976	-.37534	.43974
	Rep_3	Rep_1	.028000	.152759	.982	-.37954	.43554
		Rep_2	-.032200	.152759	.976	-.43974	.37534
LSD	Rep_1	Rep_2	-.060200	.152759	.700	-.39303	.27263
		Rep_3	-.028000	.152759	.858	-.36083	.30483
	Rep_2	Rep_1	.060200	.152759	.700	-.27263	.39303
		Rep_3	.032200	.152759	.837	-.30063	.36503
	Rep_3	Rep_1	.028000	.152759	.858	-.30483	.36083
		Rep_2	-.032200	.152759	.837	-.36503	.30063

VAR00001

	Replikas	N	Subset for alpha = 0.05
			1
Tukey HSD[a]	Replikasi_1	5	.34920
	Replikasi_3	5	.37720
	Replikasi_2	5	.40940
	Sig.		.919

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 5,000.

LAMPIRAN E
DATA KURVA BAKU DAPAR PHOSPHAT ISOTONIS PH 7,4
DENGAN TIGA KALI REPLIKASI

Pengujian hari 1	
Konsentrasi (µg/ml)	Absorbansi
2,092	0,095
8,368	0,224
14,644	0,392
20,920	0,581
27,196	0,851
a	- 0,0075
b	0,0298
r hitung	0,9808
Pengujian hari 2	
Konsentrasi (µg/ml)	Absorbansi
2,084	0,068
8,336	0,216
14,588	0,398
20,840	0,547
27,092	0,705
a	0,0123
b	0,0257
r hitung	0,9990

Pengujian hari 3	
Konsentrasi (µg/ml)	Absorbansi
2,108	0,067
8,432	0,210
14,756	0,362
21,080	0,516
27,404	0,725
a	-0,0025
b	0,0256
r hitung	0,9941

DATA ANAVA KURVA BAKU DAPAR PHOSPHAT ISOTONIS PH 7,4

Descriptives

VAR00001

Baku	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
dapar1	5	.428	.29865	.133745	.05810	.79910	.095	.851
dapar2	5	.3868	.25389	.113544	.07155	.70205	.068	.705
dapar3	5	.3760	.25721	.115029	.05663	.69537	.067	.725
Total	15	.3971	.25161	.064967	.25779	.53647	.067	.851

ANOVA

VAR00001

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	.008	2	.004	.053	.949
Within Groups	.879	12	.073		
Total	.886	14			

Multiple Comparisons

Dependent Variable:VAR00001

	(I) b_dapar	(J) b-dapar	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
LSD	dapar1	dapar2	.041800	.171135	.811	-.33107	.4146
		dapar3	.052600	.171135	.764	-.32027	.4254
	dapar2	dapar1	-.041800	.171135	.811	-.41467	.3310
		dapar3	.010800	.171135	.951	-.36207	.3836
	dapar3	dapar1	-.052600	.171135	.764	-.42547	.3202
		dapar2	-.010800	.171135	.951	-.38367	.3620

VAR00001

	baku_dapar	N	Subset for alpha = 0.05
			1
Tukey B[a]	baku_dapar3	5	.37600
	baku_dapar2	5	.38680
	baku_dapar1	5	.42860

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 5,000.

HASIL AKURASI PRESISI UJI PENETAPAN KADAR PATCH

NATRIUM DIKLOFENAK

Hasil uji akurasi dan presisi uji penetapan kadar patch natrium diklofenak dalam aquadest.

	Konsentrasi (µg/ml)	Abs	C (ppm)	C teoritis (ppm)
1	140	0,408	14,114	14,112
2	140	0,405	13,997	14,056
3	140	0,404	13,959	14,028
4	140	0,398	13,726	13,972
5	140	0,399	13,765	14
6	140	0,402	13,881	14,084
				X (%) ± SD
				KV

Contoh perhitungan :

Dari hasil serapan dimasukkan ke dalam persamaan kurva baku yang terpilih yaitu :

Y= 0,0257x + 0,044

Dimana : y = serapan

x = konsentrasi yang teramati

kemudian hitung % perolehan kembali dengan rumus :

% perolehan kembali = $\frac{konsentrasi\ teramati}{konsentrasi\ teoritis}$ X 100%

Misal data replikasi 1 :   y = 0,0257x + 0,044

0,408 = 0,0257x + 0,044

x = 14,114

% perolehan kembali = $\frac{14,114}{14,112}$ X 100 % = 100,0

HASIL AKURASI PRESISI UJI PELEPASAN DAN PENETRASI
PATCH
NATRIUM DIKLOFENAK

Hasil uji akurasi dan presisi uji pelepasan dan penetrasi patch natrium diklofenak dalam dapar phosphat isotonis pH 7,4.

	Kons (µg/ml)	Abs	C (ppm)	C teoritis (ppm)	% perolehan kembali
1	140	0,372	14,011	14,028	99,88
2	140	0,371	13,973	14,056	99,41
3	140	0,372	14,012	14,056	99,68
4	140	0,373	14,050	13,944	100,76
5	140	0,379	14,284	14,084	101,42
6	140	0,366	13,778	13,916	99,01
				X (%) ± SD	100,03 ± 0,9
				KV	0,9

Contoh perhitungan :

Dari hasil serapan dimasukkan ke dalam persamaan kurva baku yang terpilih yaitu :

Y= 0,0257x + 0,0123

Dimana : y = serapan

x = konsentrasi yang teramati

kemudian hitung % perolehan kembali dengan rumus :

% perolehan kembali = $\frac{konsentrasi\ teramati}{konsentrasi\ teoritis}$ X 100%

Misal data replikasi 1 :   y = 0,0257x + 0,0123

$$0,372 = 0,0257x + 0,0123$$

$$x = 14,011$$

% perolehan kembali $= \frac{14,011}{14,028}$ X 100 %

$$= 99,88$$

HASIL UJI PENETAPAN KADAR PATCH NATRIUM DIKLOFENAK

Formula	Uji	Absorbansi	C (ppm)	FP	C (mg/cm^2)	% kadar	X ± SD
-1	1	0,28	9,19	5	2,29	95,72	
	2	0,27	8,92	5	2,23	92,89	94,11 ± 1,46
	3	0,28	8,9	5	2,25	93,70	
a	1	0,27	8,72	5	2,18	90,88	
	2	0,27	8,80	5	2,20	91,68	91,28 ± 0,4
	3	0,27	8,76	5	2,19	91,28	
b	1	0,28	9,19	5	2,30	95,72	
	2	0,28	9,11	5	2,28	94,92	97,2 ± 3,29
	3	0,29	9,69	5	2,42	100,97	
ab	1	0,28	9,23	5	2,31	96,13	
	2	0,28	9,11	5	2,28	94,92	94,78 ± 1,42
	3	0,28	8,96	5	2,24	93,30	

% perolehan kembali = $\frac{kadar\ obat\ yang\ diperoleh}{kadar\ obat\ \ teoritis}$ X 100%

Contoh : data formula -1 replikasi 1

$= \frac{2,29}{2,4}$ x 100 % = 95,72 %

HASIL UJI HOMOGENITAS *PATCH* NATRIUM DIKLOFENAK

for	tempat pengambilan	Abs	C (ppm)	FP	C (mg/cm²)	X ± SD
-1	1	0,281	9,189	5	2,297	
	2	0,276	8,996	5	2,249	99,09 ± 7,6
	3	0,311	10,353	5	2,588	
a	1	0,269	8,724	5	2,181	
	2	0,285	9,345	5	2,336	93,43 ± 3,4
	3	0,272	8,840	5	2,210	
b	1	0,281	9,189	5	2,297	
	2	0,274	8,918	5	2,230	92,9 ± 2,8
	3	0,267	8,647	5	2,162	
ab	1	0,282	9,228	5	2,307	
	2	0,313	10,430	5	2,608	98,42 ± 9,3
	3	0,268	8,685	5	2,171	
-1	1	0,274	8,918	5	2,230	
	2	0,272	8,840	5	2,210	91,68 ± 1,4
	3	0,267	8,647	5	2,162	
a	1	0,271	8,802	5	2,200	
	2	0,313	10,430	5	2,608	98,95 ± 8,7
	3	0,283	9,267	5	2,317	
b	1	0,279	9,112	5	2,278	
	2	0,272	8,840	5	2,210	93,84 ± 1,5
	3	0,278	9,073	5	2,268	
ab	1	0,279	9,112	5	2,278	
	2	0,276	8,996	5	2,249	93,03 ±2,3
	3	0,268	8,685	5	2,171	
-1	1	0,276	8,996	5	2,249	91,95 ± 3,8

	2	0,273	8,879	5	2,220	
	3	0,266	8,608	5	2,152	
a	1	0,27	8,763	5	2,191	
	2	0,286	9,383	5	2,346	95,72 ± 3,8
	3	0,287	9,422	5	2,356	
b	1	0,294	9,693	5	2,423	
	2	0,274	8,918	5	2,230	98,82 ± 5,2
	3	0,298	9,849	5	2,462	
ab	1	0,275	8,957	5	2,239	
	2	0,314	10,469	5	2,617	98,95 ± 8,7
	3	0,278	9,073	5	2,268	

HASIL UJI KETAHANAN LIPAT *PATCH* NATRIUM DIKLOFENAK

Batch	Formula -1	Formula a	Formula b	Formula ab
1	254	261	261	287
2	253	268	256	281
3	258	262	258	289

HASIL ANAVA KETAHANAN LIPAT *PATCH* NATRIUM

DIKLOFENAK

Response   **3**   **ketahanan lipat**
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	1714.67	3	571.56	50.80	< 0.0001	significant
A-hpmc	*972.00*	*1*	*972.00*	*86.40*	*< 0.0001*	
B-ec	*481.33*	*1*	*481.33*	*42.79*	*0.0002*	
AB	*261.33*	*1*	*261.33*	*23.23*	*0.0013*	
Pure Error	90.00	8	11.25			
Cor Total	1804.6	11				

  The Model F-value of 50.80 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. 3.35	R-Squared	0.9501
Mean 265.67	Adj R-Squared	0.9314
C.V. % 1.26	Pred R-Squared	0.8878
PRESS 202.50	Adeq Precision	15.836

  The "Pred R-Squared" of 0.8878 is in reasonable agreement with the "Adj R-Squared" of 0.9314.

  "Adeq Precision" measures the signal to noise ratio. A ratio greater than

4 is desirable. Your

  ratio of 15.836 indicates an adequate signal. This model can be used to
navigate the design space.

Factor	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	265.67	1	0.97	263.4	267.90	
A-hpmc	9.00	1	0.97	6.77	11.23	1.00
B-etil selulosa	6.33	1	0.97	4.10	8.57	1.00
AB4.67		1	0.97	2.43	6.90	1.00

Final Equation in Terms of Coded Factors:

ketahanan lipat	=	
+265.67		
+9.00		* A
+6.33		* B
+4.67	* A * B	

Final Equation in Terms of Actual Factors:

ketahanan lipat	=
+265.66667	
+9.00000	* hpmc
+6.33333	* etil selulosa
+4.66667	* hpmc * etil selulosa

HASIL UJI PENETRASI PATCH NATRIUM DIKLOFENAK

Formula -1

	t (jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q (μg/cm^2)
1	0,5	0,097	3,299342	1	3,299342	17,51243
	1	0,156	5,597585	1	5,597585	29,71117
	2	0,371	13,97254	1	13,97254	74,16422
	3	0,531	20,20506	1	20,20506	107,2456
	4	0,365	13,73882	1,5	20,60823	109,3855
	5	0,387	14,59579	1,5	21,89369	116,2085
	6	0,4	15,10218	2	30,20437	160,3204
2	0,5	0,088	2,948763	1	2,948763	15,65161
	1	0,171	6,181884	1	6,181884	32,81255
	2	0,323	12,10278	1	12,10278	64,23982
	3	0,381	14,36207	1	14,36207	76,2318
	4	0,329	12,3365	1	12,3365	65,48037
	5	0,622	23,74981	1	23,74981	126,0606
	6	0,673	25,73643	1	25,73643	136,6052

	t (jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q (µg/cm²)
3	0,5	0,096	3,260389	1	3,260389	17,30567
	1	0,222	8,168501	1	8,168501	43,35722
	2	0,321	12,02487	1	12,02487	63,8263
	3	0,412	15,56962	1	15,56962	82,64131
	4	0,488	18,53007	1	18,53007	98,35494
	5	0,308	11,51848	2	23,03696	122,2769
	6	0,342	12,84289	2	25,68579	136,3364

Formula a

	t (jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q (µg/cm²)
1	0,5	0,105	3,610968	1	3,610968	19,1665
	1	0,256	9,492912	1	9,492912	50,38701
	2	0,697	26,6713	1	26,6713	141,5674
	3	0,595	22,69807	1,5	34,04711	180,7171
	4	0,492	18,68588	2	37,37177	198,364
	5	0,132	4,662707	10	46,62707	247,4897
	6	0,146	5,208052	10	52,08052	276,4359
2	0,5	0,118	4,117361	1	4,117361	21,85436
	1	0,432	16,34869	1	16,34869	86,77647
	2	0,522	19,85448	1	19,85448	105,3847

98

	t (jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q (µg/cm²)
	3	0,543	20,6725	1	20,6725	109,7267
	4	0,389	14,6737	3	44,02109	233,6576
	5	0,213	7,817921	6	46,90753	248,9784
	6	0,244	9,025473	6	54,15284	287,4354
3	0,5	0,153	5,480725	1	5,480725	29,0909
	1	0,553	21,06203	1	21,06203	111,7942
	2	0,623	23,78876	1	23,78876	126,2673
	3	0,475	18,02368	1,5	27,03552	143,5006
	4	0,549	20,90622	1,5	31,35933	166,4508
	5	0,325	12,18069	4	48,72275	258,6133
	6	0,393	14,82951	4	59,31804	314,8516

Formula b

	t (jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q (µg/cm²)
1	0,5	0,151	5,402819	1	5,402819	28,67738
	1	0,435	16,46555	1	16,46555	87,39675
	2	0,588	22,4254	1	22,4254	119,0308
	3	0,181	6,571417	3	19,71425	104,6404
	4	0,428	16,19287	1,5	24,28931	128,9242

	5	0,287	10,70046	4	42,80185	227,1861
	6	0,31	11,59639	4	46,38556	246,2078
2	0,5	0,291	10,85628	1	10,85628	57,62355
	1	0,371	13,97254	1	13,97254	74,16422
	2	0,312	11,6743	1,5	17,51144	92,94821
	3	0,239	8,830707	2	17,66141	93,74423
	4	0,253	9,376052	2	18,7521	99,53346
	5	0,386	14,55684	2	29,11367	154,5312
	6	0,328	12,29755	5	61,48774	326,368
3	0,5	0,272	10,11616	1	10,11616	53,69514
	1	0,323	12,10278	1	12,10278	64,23982
	2	0,426	16,11497	1	16,11497	85,53592
	3	0,65	24,8405	1	24,8405	131,8498
	4	0,346	12,99871	2	25,99741	137,9905
	5	0,532	20,24401	2	40,48803	214,9046
	6	0,658	25,15213	2	50,30425	267,0077

Formula ab

	t(jam)	Abs sampel	C sampel (ppm)	Fp	C sebenarnya (ppm)	Q ($\mu g/cm^2$)
1	0,5	0,138	4,896426	1	4,896426	25,98952
	1	0,308	11,51848	1	11,51848	61,13844
	2	0,287	10,70046	4	42,80185	227,1861
	3	0,384	14,47893	4	57,91572	307,4083
	4	0,408	15,41381	4	61,65524	327,2571
	5	0,43	16,27078	4	65,08313	345,4518
	6	0,617	23,55504	4	94,22017	500,1071
2	0,5	0,157	5,636538	1	5,636538	29,91793
	1	0,368	13,85568	1	13,85568	73,54394
	2	0,315	11,79116	2	23,58231	125,1715
	3	0,397	14,98532	2	29,97065	159,0799
	4	0,557	21,21785	2	42,43569	225,2425
	5	0,581	22,15273	3	66,45818	352,7504
	6	0,606	23,12656	4	92,50623	491,0097
3	0,5	0,219	8,051641	1	8,051641	42,73695
	1	0,477	18,10159	1	18,10159	96,0806
	2	0,546	20,78936	1	20,78936	110,3469

101

3	0,554	21,10099	2	42,20197	224,002
4	0,463	17,55624	2	35,11248	186,372
5	0,547	20,82831	3	62,48494	331,6611
6	0,669	25,58061	4	102,3225	543,1128

ANALISIS ANAVA PELEPASAN DENGAN FAKTORIAL DESIGN

.

Response **1** **pelepasan**
   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	1565.15	3	521.72	522.25	< 0.0001	significant
A-hpmc	*1380.95*	*1*	*1380.95*	*1382.37*	*< 0.0001*	
B-etil selulosa	*180.58*	*1*	*180.58*	*180.76*	*< 0.0001*	
AB	*3.62*	*1*	*3.62*	*3.62*	*0.0935*	
Pure Error	7.99	8	1.00			
Cor Total	1573.14	11				

   The Model F-value of 522.25 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 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.	1.00	R-Squared	0.9949
Mean	44.58	Adj R-Squared	0.9930
C.V. %	2.24	Pred R-Squared	0.9886
PRESS	17.98	Adeq Precision	50.625

   The "Pred R-Squared" of 0.9886 is in reasonable agreement with the "Adj R-Squared" of 0.9930.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your
ratio of 50.625 indicates an adequate signal. This model can be used to navigate the design space.

Coefficient Factor	Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	44.58	1	0.29	43.91	45.24	
A-hpmc	10.73	1	0.29	10.06	11.39	1.00
B-etil selulosa	3.88	1	0.29	3.21	4.54	1.00
AB	-0.55	1	0.29	-1.21	0.12	1.00

Final Equation in Terms of Coded Factors:

pelepasan   =
+44.58
+10.73   * A
+3.88   * B
-0.55   * A * B

Final Equation in Terms of Actual Factors:

pelepasan   =
+44.57917
+10.72750   * hpmc
+3.87917   * etil selulosa
-0.54917   * hpmc * etil selulosa

ANALISIS ANAVA PENETRASI DENGAN FAKTORIAL DESIGN

Response   2   penetrasi
  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	27813.07	3	9271.02	197.65	< 0.0001	signific
A-hpmc	18447.52	1	18447.52	393.29	< 0.0001	
B-etil selulosa	8574.98	1	8574.98	182.81	< 0.0001	
AB	790.56	1	790.56	16.85	0.0034	
Pure Error	375.25	8	46.91			
Cor Total	28188.32	11				

   The Model F-value of 197.65 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.	6.85	R-Squared	0.9867
Mean	117.23	Adj R-Squared	0.9817
C.V. %	5.84	Pred R-Squared	0.9700
PRESS	844.31	Adeq Precision	33.352

   The "Pred R-Squared" of 0.9700 is in reasonable agreement with the "Adj R-Squared" of 0.9817.

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

ratio of 33.352 indicates an adequate signal. This model can be used to navigate the design space.

Coefficient Factor	Standard Estimate	df	Error	95% CI Low	95% CI High
Intercept	117.23	1	1.98	112.67	121.79
A-hpmc	39.21	1	1.98	34.65	43.77
B-etil selulosa	26.73	1	1.98	22.17	31.29
AB	8.12	1	1.98	3.56	12.68

Final Equation in Terms of Coded Factors:

penetrasi	=
+117.23	
+39.21	* A
+26.73	* B
+8.12	* A * B

Final Equation in Terms of Actual Factors:

penetrasi	=
+117.22667	
+39.20833	* hpmc
+26.73167	* etil selulosa
+8.11667	* hpmc * etil selulosa

LAMPIRAN P

TABEL R

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

TABEL UJI F

Denomins for Degrees of Freedom	Numerator Degrees of Freedom								
	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	18.81	19.00	19.16	19.25	19.30	19.33	19.35	19.37	19.38
3	10.73	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

(Sumber: John E., 1992)

NATRIUM DIKLOFENAK

Wenzhou Pharmaceutical Factory

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Tel: +86-577-8852 0260   8852 5636   Fax: +86-577-8851 6775
Web Site: http://www.wpf.com   E-mail: wpf@mail.wzptt.zj.cn

Certificate of Analysis

Product: **Diclofenac Sodium BP98**   Quantity: 300kgs

Batch NO.: 20031226-1   Manuf Date: Dec. 2010

Specification: BP98   Expiry Date: Dec. 2014

Test	Result	Specification
Characteristics	Complies	A white or slightly yellowish crystalline powder
Identification	Complies	A.IR
	Complies	B.Test of sodium salt
Appearance of solution	0.013	5.0% of methanolic solution,UV 440nm.NMT 0.05
Related substances	< 0.2%	Individual impurity ≤0.2%
	< 0.5%	Total impurity ≤0.5%
Heavy metals	<10ppm	≤10ppm
Loss on drying	0.25%	≤0.5%
Acidity or alkalinity	7.27	7.0~8.5
Assay (on dry basis)	99.45%	99.0-101.0%

Comments: Comply with the requirements of: BP98

Signature:

Analyst: 刘诗文芳   Approver: 姜小琴

HPMC K-4M

DOW

Certificate 4962367   The Dow Chemical Company   Page   1
Date: 16.08.2010   Certificate of Analysis   Shipped: 16.08.2010
File Copy
DOW CHEMICAL PACIFIC LIMITED   Fax: COA ARCHIVE
SHANGHAI PUDONG AIRPORT
SHANGHAI   SG 200004   CHINA
Cust P.O.: 040/85/40183214   Dlvy Note: 70695422 10
Material: METHOCEL* K4M Premium
            Hydroxypropyl Methylcellulose   Spec: 00053981-S
Batch: YG13012N01   Mfgd: 13.07.2010   Retest Date: 12.07.2015
Ship from: THE DOW CHEMICAL COMPANY   BAY CITY   MI UNITED STATES

It is hereby certified the material indicated above has been manu-
factured in accordance with the FDA's Current Good Manufacturing
Practices, Kosher guidelines, was inspected and tested in accordance
with the conditions and the requirements of current USP, EP and JP
for Hypromellose as well as the current specific purity criteria for
the food additive Hydroxypropyl Methyl Cellulose (E464) and unless
agreed otherwise, conforms in all respects to the specification
relevant thereto.

Feature	Units	Results YG13012N01	Minimum	Maximum
Apparent Viscosity	mPa.s	3,298	2,663	4,970
Loss on Drying	%	3.2	----	5.0
Residue on Ignition	%	0.5	----	1.5
Ash, Sulfated	%	0.5	----	1.5
pH, 2% in Water	-	6.3	5.0	8.0
Assay, Methoxyl	%	22.6	19.0	24.0
Assay, Hydroxypropoxyl	%	8.6	7.0	12.0
Appearance, Opalescence		Passes	----	----
Appearance, Solution Color		Passes	----	----

Typical Properties: This batch, based on audit testing and process control,
complies with the following additional specification requirements:
     Harmonized Identification Tests: Passes
     Residual Solvents: Passes
     Heavy Metals as PB: Not more than 20 ppm
     Microbiological Limits: Passes
Batch (Lot) Number manufactured location: 2N = Midland, MI; 24 = Plaquemine, LA

Julie Wright, PORTEFIBER, METHOCEL Quality Systems Specialist
For inquiries please contact Customer Service at 1-800-232-2436 (USA).

* Trademark of The Dow Chemical Company

ETIL SELULOSA

```
Certificate 5693427        The Dow Chemical Company
Date:  27.04.2012        Certificate of Analysis        Shipped:  2
File Copy
DOW CHEMICAL PACIFIC LIMITED        Fax: COA ARCHIVE
SHANGHAI PUDONG AIRPORT
SHANGHAI                 SG 201202        CHINA
Cust P.O.:  040/85/40211021                Dlvy Note: 71
Material:  ETHOCEL* Standard 20 Premium
           Ethylcellulose                  Spec:   0002
Cust Mtl:
Batch:   1A24013T01   Mfgd:    24.01.2012   Retest Date:  2
Ship from: THE DOW CHEMICAL COMPANY      BAY CITY       MI UNITED
It is hereby certified that the lot of material listed above has bee
manufactured in accordance with U.S. FDA current Good Manufacturing
Practices. In addition, the manufacturing facility and this product
been Kosher certified. Unless stated otherwise, the material complie
with all applicable sales and/or customer specifications and in addi
meets the monograph limits for ethylcellulose provided in the curren
National Formulary (USP/NF), Food Chemical Codex, European
Pharmacopoeia, and Japanese Pharmaceutical Excipients associated wit
the current Japanese Pharmacopoeia, European Parliament and Council
Directive for ethylcellulose (E462).
```

Feature	Units	Results 1A24013T01	Limits Minimum	Maximum	Method
Viscosity	mPa.s	21.2	18.0	22.0	Current
Ethoxyl Content assay	% wt	49.0	48.0	49.5	Current
Loss on Drying moisture	% wt	0.3	----	2.0	Current
Chloride (as NaCl)	% wt	0.02	----	0.05	Current
Residue on Ignition	% wt	0.22	----	0.40	Current

```
This lot of material, based on quarterly audit testing of
representative lots of the product, also complies with the following
additional specification requirements: Aldehydes, 100 ppm Max; Arsen
2 ppm Max; Lead, 2 ppm Max;  Cadmium, 1 ppm Max; Mercury, 1 ppm Max;
Heavy Metals, 20 ppm Max; Acidity or Alkalinity, Passes; Residual
Solvents, Passes; pH - 1% Collodial Solution, Passes; ID Test NF,
Passes; ID Test A-EP, Passes; ID Test B-EP, Passes; ID Test 1-JPE,
Passes; ID Test 2-JPE, Passes; ID FCC, Passes; ID Test A-E462,
Passes; ID Test B - E462, Passes; Total Aerobic Microbial Count,
100 CFU/g Max; Total Combined Yeast & Mold Count, 100 CFU/g Max;
Staphylococcus Aureus, Negative; Pseudomonas Aeruginosa, Negative;
Salmonella Species, negative; Escherichia Coli, Negative.
```

METHANOL

CERTIFICATE OF ANALYSIS

Doc. No. : 491/COA/ /XI/12
Product Name : Methanol
MAP Code : 491/IM.4601.5401 - 07/11/12
Received Date : November 7, 2012
Expiry Date : No Expiry

: 2 3 NOV 2012

Delivery Date :
No. Lot / Batch :
Quantity :

The above samples were analysed and the following results have been obtained :

NO.	ANALYSIS ITEM	REFERENCE	UNIT	SPECIFICATION	RESULT
1	Appearance	VISUAL		Clear	Clear
2	Color	ASTM D - 1209	Pt-Co	Max. 5	3
3	Specific Gravity at 20°C / 4°C	ASTM D – 891		0.791 - 0.793	0.7920
	Specific Gravity at 28°C / 4°C	ASTM D – 891			0.7845
	Specific Gravity at 30°C / 4°C	ASTM D – 891			0.7825
4	Initial Boiling Point (IBP)	ASTM D-1078	°C	64.6 ± 0.1 (Max. 1)	64.5
5	Dry Point (DP)	ASTM D-1078	°C		65.0
6	Water Content	ASTM D – 1364	wt%	Max. 0.1	0.02
7	Purity	Gas Chromatography	wt %	Min. 99.85	99.97
8	Permanganate time at 15 ° C	ASTM D-1363	Minutes	More Than 50	More Than 50

Remark :
This Certificate refers to the tested sample only.
Jakarta, November 8, 2012

KLOROFORM

PT.BRATACO

HASIL PEMERIKSAAN

Nama Bahan : Chloroform
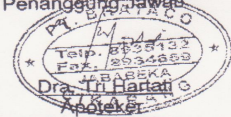Batch : J 0122/11 (33685)
Ex : Biesterfeld
Grade : teknik

Jenis pemeriksaan	Persyaratan FI III	Hasil
Pemerian	Cairan jernih, tidak berwarna,mudah mengalir, mempunyai sifat khas,bau eter,rasa manis dan membakar	sesuai
Kelarutan	Sukar larut dalam air, dapat bercampur dengan etanol, eter, benzene, hexsan, dan dengan minyak lemak serta minyak menguap	sesuai
Klor bebas	Pada 10 ml tambahkan 10 ml air dan 0,1 ml *Kalium Iodida* LP,kocok selama 2 menit dan biarkan memisah,lapisan bawah tidak berwarna ungu	sesuai
Hasil Peruraian	Lapisan asam tidak menunjukkan perubahan warna	sesuai
Bobot jenis	Antara 1,476 dan 1,4886 g/ml	1,477

Kesimpulan : *Memenuhi syarat*

Cikarang, 07-05-2011
Penanggung Jawab

Pemeriksa

Tatang Suhartono
Analis

Dra. Tri Hartati
Apoteker
S.I.K. 3836/B