

## **BAB V**

### **KESIMPULAN DAN SARAN**

#### **A. Kesimpulan**

1. Na-CMC dan xanthan gum berpengaruh terhadap sifat fisik granul dan tablet lepas lambat salbutamol sulfat :
  - a. Xanthan gum merupakan faktor yang berpengaruh sangat dominan dalam meningkatkan sifat alir massa tablet lepas lambat salbutamol sulfat.
  - b. Na-CMC merupakan faktor yang berpengaruh sangat dominan dalam meningkatkan kompaktibilitas massa tablet lepas lambat salbutamol sulfat.
  - c. Kombinasi xanthan gum dan Na-CMC mempengaruhi kecepatan disolusi salbutamol sulfat dengan sedikit lebih banyak jumlah xanthan gum, maka pelepasan menjadi semakin efisien dan penyerapan air semakin sedikit sehingga waktu hancur tablet menjadi lama
2. Berdasarkan data *simplex lattice design*, perbandingan 41,94% Na-CMC dan 58,06% xanthan gum merupakan formula yang optimum dan pola pelepasannya mengikuti orde nol.

#### **B. Saran**

1. Perlu dilakukan penelitian lebih lanjut dengan parameter yang diuji seperti kandungan zat aktif dan kelembapan granul.
2. Perlu dilakukan penelitian lanjutan untuk sediaan lepas lambat salbutamol sulfat dengan uji disolusi penambahan waktu sampling dengan dosis yang sama serta dilakukan uji pelepasan obatnya secara *in vivo*.

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### Lampiran 1. Perhitungan dosis salbutamol sulfat dalam tablet lepas lambat

Dosis lazim salbutamol sulfat (DL) = 4 mg tiap kali minum

Waktu disolusi yang diharapkan (t) = 12 jam

Waktu paro salbutamol sulfat ( $t_{1/2}$ ) = 2,7 jam

$$K = \frac{0,693}{t_{1/2}} = \frac{0,693}{2,7} = 0,2567 \text{ /jam}$$

Dosis salbutamol sulfat = DL x k x t  
 = 4 mg x 0,2567 x 12 jam = 12,32 mg

Dosis salbutamol sulfat dalam tablet dibulatkan menjadi = 12 mg / tablet

### Lampiran 2. Waktu alir granul

Formula I

Formula	Waktu (detik)			Rata-rata ± SD
	Replikasi 1	Replikasi 2	Replikasi 3	
I	7,2	7,8	7,4	7,4 ± 0,301
II	6,3	6,9	6,6	6,6 ± 0,3
III	5,6	5,8	6,2	5,86 ± 0,306
IV	10,7	10,2	9,4	10,2 ± 0,5

### Lampiran 3. Sudut diam

Rumus sudut diam =  $\text{archtan} \frac{\text{jari} - \text{jari}}{\text{tinggi}}$

Formula I

Tinggi (cm)	Jari-jari (cm)	Sudut diam
3,61	5,71	32,32
3,58	5,70	32,16
3,42	5,74	30,81
Rata-rata		31,76
SD		0,83

Formula II

Tinggi (cm)	Jari-jari (cm)	Sudut diam
2,92	5,32	28,77
2,83	4,97	29,73
2,70	4,85	29,10
Rata-rata		29,2
SD		0,488

## Formula III

Tinggi (cm)	Jari-jari (cm)	Sudut diam
3,14	6,06	27,35
3,11	5,97	27,54
3,12	6,01	27,46
Rata-rata		27,45
SD		0,095

## Kontrol

Tinggi (cm)	Jari-jari (cm)	Sudut diam
2,72	4,82	29,44
2,73	4,64	30,47
2,73	4,75	29,89
Rata-rata		29,93
SD		0,52

**Lampiran 4. Daya serap**

## Formula I

Berat granul + botol timbang	5 menit	10 menit	15 menit	Daya serap air
22,5345	22,6311	22,6329	22,6339	0,0994
22,5350	22,6224	22,6242	22,6246	0,0896
22,5312	22,6325	22,6327	22,6365	0,1053
Rata-rata				0,0981
SD				0,008

## Formula II

Berat granul + botol timbang	5 menit	10 menit	15 menit	Daya serap air
22,8935	22,9370	22,9389	22,9400	0,0465
22,8785	22,9178	22,9198	22,9217	0,0432
22,8970	22,9356	22,9368	22,9372	0,0402
Rata-rata				0,0433
SD				0,0031

## Formula III

Berat granul + botol timbang	5 menit	10 menit	15 menit	Daya serap air
22,5676	22,6188	22,6252	22,6261	0,0585
22,5629	22,6212	22,6239	22,6246	0,0617
22,5652	22,6246	22,6258	22,6271	0,0619
Rata-rata				0,0607
SD				0,0019

Kontrol				
Berat granul + botol timbang	5 menit	10 menit	15 menit	Daya serap air
15,4154	15,7417	15,8836	15,8840	0.4686
15,4301	15,6891	15,8275	15,8284	0.3983
15,4333	15,6799	15,8519	15,8524	0.4191
Rata-rata				0.4287
SD				0.036

### Lampiran 5. Penetapan

#### Formula I

Volume awal (Vo)	Volume akhir (Vt)	Indeks tap $\left\{ \frac{(Vt-Vo)}{Vo} \times 100\% \right\}$
100 ml	95 ml	5%
100 ml	95 ml	5%
100 ml	95 ml	5%
Rata-rata		5%
SD		0

#### Formula II

Volume awal (Vo)	Volume akhir (Vt)	Indeks tap $\left\{ \frac{(Vt-Vo)}{Vo} \times 100\% \right\}$
100 ml	91 ml	9%
100 ml	92 ml	8%
100 ml	91 ml	9%
Rata-rata		8,67%
SD		0,58

#### Formula III

Volume awal (Vo)	Volume akhir (Vt)	Indeks tap $\left\{ \frac{(Vt-Vo)}{Vo} \times 100\% \right\}$
100 ml	97 ml	3%
100 ml	97 ml	3%
100 ml	96 ml	4%
Rata-rata		3,33%
SD		0,58

**Kontrol**

Volume awal (Vo)	Volume akhir (Vt)	Indeks tap $\left\{ \frac{(Vt-Vo)}{Vo} \times 100\% \right\}$
100 ml	94 ml	6%
100 ml	95 ml	5%
100 ml	95 ml	5%
Rata-rata		5,3%
SD		0,58

**Lampiran 6. Kompaktibilitas**

Formula	kekerasan (kg)			Rata-rata ± SD
	Replikasi 1	Replikasi 2	Replikasi 3	
I	14,5	14,5	14,3	14,43±0,115
II	13,9	14,2	14,1	14,07±0,153
III	14,1	14,3	14	14,13±0,153
Kontrol	9,5	9,5	9,6	9,55±0,057

**Lampiran 7. Kerapuhn**

Formula	kerapuhan (%)			Rata-rata ± SD
	Replikasi 1	Replikasi 2	Replikasi 3	
I	0,5	0,3	0,2	0,33±0,15
II	0,4	0,5	0,7	0,53±0,15
III	0,6	0,4	0,4	0,46±0,12
Kontrol	0,6	0,7	0,6	0,63±0,57



**Lampiran 8. Keseragaman bobot**

Replikasi	Formula I	Formula II	Formula III	Kontrol
1	202	201	204	196
2	200	202	207	195
3	205	203	209	197
4	200	203	199	212
5	220	206	202	191
6	203	207	206	197
7	199	207	204	197
8	208	209	207	197
9	198	203	204	198
10	197	203	204	203
11	201	200	209	202
12	201	205	208	197
13	209	199	207	198
14	199	205	206	195
15	199	199	209	199
16	204	199	208	198
17	200	200	205	197
18	206	204	204	200
19	209	209	200	198
20	209	202	204	199
Rata-rata	203,45	203,3	205,3	198,3
SD	5,51	3,18	2,85	4,092
CV	2,71%	1,56%	1,39%	2,064

### Lampiran 9. Penentuan panjang gelombang maksimum dan pembuatan kurva baku salbutamol sulfat

Penentuan panjang gelombang maksimum

Panjang gelombang (nm)	Absorbansi
255	0.156
260	0.252
265	0.384
270	0.532
275	0.633
280	0.605
285	0.403
290	0.127
295	0.034
300	0.021
305	0.019
310	0.019
315	0.019
320	0.019
325	0.018
330	0.018
335	0.017
340	0.018
345	0.017
350	0.016

Panjang gelombang maksimum salbutamol sulfat adalah 276 nm

Pembuatan larutan induk salbutamol sulfat

Penimbangan bahan

Ketas timbang + zat = 0,3979 g

Kertas timbang + sisa = 0,2979 g -

Bobot zat = 0,100 g

Kadar salbutamol sulfat = 0,100 g / 100 ml = 100 mg/100ml = 1 mg/ml

❖ Konsentrasi 25 ppm

$$\begin{aligned}
 V1 \times N1 &= V2 \times N2 \\
 100 \text{ ml} \times 25 \text{ ppm} &= V2 \times 1000 \text{ ppm} \\
 V2 &= \frac{2500 \text{ ppm}}{1000 \text{ ppm}} \\
 V2 &= 2,5 \text{ ml}
 \end{aligned}$$

## ❖ Konsentrasi 50 ppm

$$\begin{aligned}
 V1 \times N1 &= V2 \times N2 \\
 100 \text{ ml} \times 50 \text{ ppm} &= V2 \times 1000 \text{ ppm} \\
 V2 &= \frac{5000 \text{ ppm}}{1000 \text{ ppm}} \\
 V2 &= 5 \text{ ml}
 \end{aligned}$$

## ❖ Konsentrasi 75 ppm

$$\begin{aligned}
 V1 \times N1 &= V2 \times N2 \\
 100 \text{ ml} \times 75 \text{ ppm} &= V2 \times 1000 \text{ ppm} \\
 V2 &= \frac{7500 \text{ ppm}}{1000 \text{ ppm}} \\
 V2 &= 7,5 \text{ ml}
 \end{aligned}$$

## ❖ Konsentrasi 100 ppm

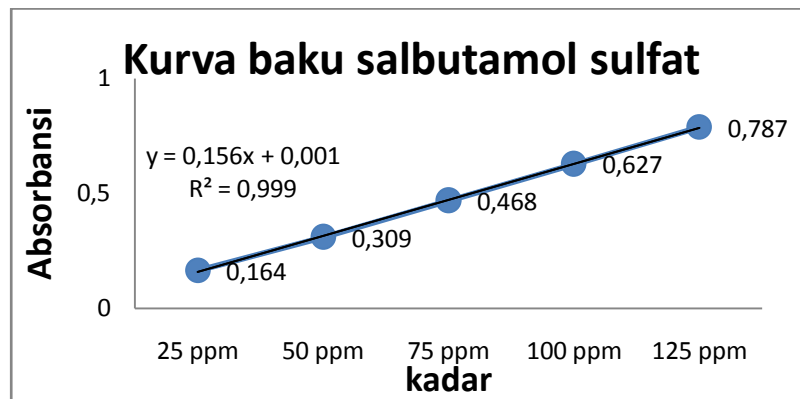
$$\begin{aligned}
 V1 \times N1 &= V2 \times N2 \\
 100 \text{ ml} \times 100 \text{ ppm} &= V2 \times 1000 \text{ ppm} \\
 V2 &= \frac{10000 \text{ ppm}}{1000 \text{ ppm}} \\
 V2 &= 10 \text{ ml}
 \end{aligned}$$

## ❖ Konsentrasi 125 ppm

$$\begin{aligned}
 V1 \times N1 &= V2 \times N2 \\
 100 \text{ ml} \times 125 \text{ ppm} &= V2 \times 1000 \text{ ppm} \\
 V2 &= \frac{12500 \text{ ppm}}{1000 \text{ ppm}} \\
 V2 &= 12,5 \text{ ml}
 \end{aligned}$$

Data kurva baku salbutamol sulfat

Kadar (mg/ml)	Absorbansi
0,025	0,164
0,050	0,309
0,075	0,468
0,100	0,627
0,125	0,787



Data regresi linier

$$A = 1,8 \times 10^{-3}$$

$$B = 6,256 \times 10^{-3}$$

$$r = 0,9998$$

$$\text{Persamaan regresi linier } y = 1,8 \times 10^{-3} + 6,256 \times 10^{-3}x$$

### Lampiran 10. Perhitungan kadar salbutamol sulfat

Rumus perhitungan

$$\text{kadar salbutamol sulfat} : \frac{\text{kadar (mg/ml)} \times \text{volum media disolusi}}{\text{dosis salbutamol sulfat dalam 1 tablet}} \times 100\%$$

Volum media disolusi : 900 ml

Dosis salbutamol sulfat 1 tablet : 400 mg

#### Formula I Replikasi 1

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,02	0,0029	2,6181	21,82
60	0,022	0,0032	2,9058	24,21
90	0,026	0,0039	3,4812	29,01
120	0,036	0,0055	4,9197	41,00
150	0,051	0,0079	7,0774	58,98
180	0,033	0,0050	4,4881	37,40
210	0,035	0,0053	4,7758	39,80
240	0,036	0,0055	4,9197	41,00
270	0,038	0,0058	5,2074	43,39
300	0,039	0,0059	5,3512	44,59
330	0,04	0,0061	5,4951	45,79
360	0,042	0,0064	5,7828	48,19

Formula I Replikasi 2

Waktu (menit)	Absorbansi	Kadar (mg/ml)	kadar dalam 900 ml	Kadar (%)
30	0,016	0,0023	2,0427	17,02
60	0,018	0,0026	2,3304	19,42
90	0,024	0,0035	3,1935	26,61
120	0,026	0,0039	3,4812	29,01
150	0,029	0,0043	3,9127	32,61
180	0,031	0,0047	4,2004	35,00
210	0,034	0,0051	4,6320	38,60
240	0,036	0,0055	4,9197	41,00
270	0,037	0,0056	5,0635	42,20
300	0,038	0,0058	5,2074	43,39
330	0,042	0,0064	5,7828	48,19
360	0,043	0,0066	5,9266	49,39

Formula I Replikasi 3

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,018	0,0026	2,3304	19,42
60	0,02	0,0029	2,6181	21,82
90	0,025	0,0037	3,3373	27,81
120	0,028	0,0042	3,7689	31,41
150	0,025	0,0037	3,3373	27,81
180	0,044	0,0067	6,0705	50,59
210	0,048	0,0074	6,6459	55,38
240	0,048	0,0074	6,6459	55,38
270	0,051	0,0079	7,0774	58,98
300	0,052	0,0080	7,2213	60,18
330	0,056	0,0087	7,7967	64,97
360	0,059	0,0091	8,2282	68,57

## Rata-rata kadar salbutamol sulfat formula I

Replikasi 1	Replikasi 2	Replikasi 3	Rata-rata kadar (%)
21,82	17,02	19,42	19,42
24,21	19,42	21,82	21,82
29,01	26,61	27,81	27,81
41,00	29,01	31,41	33,80
58,98	32,61	27,81	39,80
37,40	35,00	50,59	41,00
39,80	38,60	55,38	44,59
41,00	41,00	55,38	45,79
43,39	42,20	58,98	48,19
44,59	43,39	60,18	49,39
45,79	48,19	64,97	52,98
48,19	49,39	68,57	55,38

## Formula II Replikasi 1

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,014	0,0019	1,7550	14,62
60	0,019	0,0027	2,4742	20,62
90	0,024	0,0035	3,1935	26,61
120	0,025	0,0037	3,3373	27,81
150	0,029	0,0043	3,9127	32,61
180	0,031	0,0047	4,2004	35,00
210	0,032	0,0048	4,3443	36,20
240	0,032	0,0048	4,3443	36,20
270	0,033	0,0050	4,4881	37,40
300	0,035	0,0053	4,7758	39,80
330	0,037	0,0056	5,0635	42,20
360	0,039	0,0059	5,3512	44,59

Formula II Replikasi 2

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,011	0,0015	1,3234	11,03
60	0,017	0,0024	2,1865	18,22
90	0,02	0,0029	2,6181	21,82
120	0,024	0,0035	3,1935	26,61
150	0,027	0,0040	3,6250	30,21
180	0,029	0,0043	3,9127	32,61
210	0,03	0,0045	4,0566	33,80
240	0,03	0,0045	4,0566	33,80
270	0,031	0,0047	4,2004	35,00
300	0,031	0,0047	4,2004	35,00
330	0,032	0,0048	4,3443	36,20
360	0,033	0,0050	4,4881	37,40

Formula II Replikasi 3

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,008	0,0010	0,8919	7,43
60	0,012	0,0016	1,4673	12,23
90	0,016	0,0023	2,0427	17,02
120	0,02	0,0029	2,6181	21,82
150	0,028	0,0042	3,7689	31,41
180	0,03	0,0045	4,0566	33,80
210	0,034	0,0051	4,6320	38,60
240	0,037	0,0056	5,0635	42,20
270	0,038	0,0058	5,2074	43,39
300	0,039	0,0059	5,3512	44,59
330	0,042	0,0064	5,7828	48,19
360	0,042	0,0064	5,7828	48,19

## Rata- rata kadar salbutamol sulfat formula II

Replikasi 1	Replikasi 2	Replikasi 3	Rata-rata kadar (%)
14,62	11,03	11,03	11,03
20,62	18,22	18,22	17,02
26,61	21,82	21,82	21,82
27,81	26,61	26,61	25,41
32,61	30,21	30,21	31,41
35,00	32,61	32,61	33,80
36,20	33,80	33,80	36,20
36,20	33,80	33,80	37,40
37,40	35,00	35,00	38,60
39,80	35,00	35,00	39,80
42,20	36,20	36,20	42,20
44,59	37,40	37,40	43,39

## Formula III Replikasi 1

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,012	0,0016	1,4673	12,23
60	0,02	0,0029	2,6181	21,82
90	0,028	0,0042	3,7689	31,41
120	0,03	0,0045	4,0566	33,80
150	0,033	0,0050	4,4881	37,40
180	0,035	0,0053	4,7758	39,80
210	0,036	0,0055	4,9197	41,00
240	0,036	0,0055	4,9197	41,00
270	0,037	0,0056	5,0635	42,20
300	0,039	0,0059	5,3512	44,59
330	0,04	0,0061	5,4951	45,79
360	0,04	0,0061	5,4951	45,79



Formula III Replikasi 2

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,011	0,0015	1,3234	11,03
60	0,014	0,0019	1,7550	14,62
90	0,016	0,0023	2,0427	17,02
120	0,019	0,0027	2,4742	20,62
150	0,022	0,0032	2,9058	24,21
180	0,023	0,0034	3,0496	25,41
210	0,026	0,0039	3,4812	29,01
240	0,027	0,0040	3,6250	30,21
270	0,03	0,0045	4,0566	33,80
300	0,031	0,0047	4,2004	35,00
330	0,034	0,0051	4,6320	38,60
360	0,036	0,0055	4,9197	41,00

Formula III Replikasi 3

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,016	0,0023	2,0427	17,02
60	0,023	0,0034	3,0496	25,41
90	0,025	0,0037	3,3373	27,81
120	0,029	0,0043	3,9127	32,61
150	0,035	0,0053	4,7758	39,80
180	0,036	0,0055	4,9197	41,00
210	0,037	0,0056	5,0635	42,20
240	0,039	0,0059	5,3512	44,59
270	0,041	0,0063	5,6389	46,99
300	0,041	0,0063	5,6389	46,99
330	0,043	0,0066	5,9266	49,39
360	0,044	0,0067	6,0705	50,59

## Rata-rata kadar salbutamol sulfat formula III

Replikasi 1	Replikasi 2	Replikasi 3	Rata-rata kadar (%)
12,23	11,03	17,02	13,43
21,82	14,62	25,41	20,62
31,41	17,02	27,81	25,41
33,80	20,62	32,61	29,01
37,40	24,21	39,80	33,80
39,80	25,41	41,00	35,40
41,00	29,01	42,20	37,40
41,00	30,21	44,59	38,60
42,20	33,80	46,99	41,00
44,59	35,00	46,99	42,20
45,79	38,60	49,39	44,59
45,79	41,00	50,59	45,79

## Persamaan Regresi linier waktu dan kadar

Formula	Persamaan regresi linier	r
Formula I	$Y = 19,075 + 0,0107X$	0,975
Formula II	$Y = 13,446 + 0,0926X$	0,961
Formula III	$Y = 16,497 + 0,0892X$	0,964

## Formula Kontrol Replikasi 1

Waktu (menit)	Absorbansi	Kadar (ppm)	Kadar (mg/ml)	Kadar 900ml	Kadar %
30	0.032	4.8270	0.0048	4.3443	36.20
60	0.044	6.7450	0.0067	6.0705	50.59
90	0.059	9.1425	0.0091	8.2282	68.57
120	0.067	10.4212	0.0104	9.3790	78.16
150	0.075	11.6998	0.0117	10.5298	87.75
180	0.081	12.6588	0.0127	11.3930	94.94
210	0.083	12.9785	0.0130	11.6807	97.34
240	0.08	12.4990	0.0125	11.2491	93.74
270	0.084	13.1383	0.0131	11.8245	98.54
300	0.08	12.4990	0.0125	11.2491	93.74
330	0.076	11.8597	0.0119	10.6737	88.95
360	0.069	10.7408	0.0107	9.6667	80.56

## Formula kontrol Replikasi 2

Waktu (menit)	Absorbansi	Kadar (ppm)	Kadar (mg/ml)	Kadar 900ml	Kadar %
30	0.035	5.3065	0.0053	4.7758	39.80
60	0.048	7.3843	0.0074	6.6459	55.38
90	0.058	8.9827	0.0090	8.0844	67.37
120	0.069	10.7408	0.0107	9.6667	80.56
150	0.079	12.3392	0.0123	11.1053	92.54
180	0.082	12.8187	0.0128	11.5368	96.14
210	0.084	13.1383	0.0131	11.8245	98.54
240	0.08	12.4990	0.0125	11.2491	93.74
270	0.086	13.4580	0.0135	12.1122	100.94
300	0.079	12.3392	0.0123	11.1053	92.54
330	0.078	12.1793	0.0122	10.9614	91.35
360	0.071	11.0605	0.0111	9.9544	82.95

## Formula Kontrol Replikasi 3

Waktu (menit)	Absorbansi	Kadar (ppm)	Kadar (mg/ml)	Kadar 900ml	Kadar %
30	0.035	5.3065	0.0053	4.7758	39.80
60	0.049	7.5442	0.0075	6.7897	56.58
90	0.06	9.3023	0.0093	8.3721	69.77
120	0.071	11.0605	0.0111	9.9544	82.95
150	0.077	12.0195	0.0120	10.8175	90.15
180	0.086	13.4580	0.0135	12.1122	100.94
210	0.085	13.2982	0.0133	11.9684	99.74
240	0.083	12.9785	0.0130	11.6807	97.34
270	0.085	13.2982	0.0133	11.9684	99.74
300	0.081	12.6588	0.0127	11.3930	94.94
330	0.071	11.0605	0.0111	9.9544	82.95
360	0.07	10.9007	0.0109	9.8106	81.75

## Rata-rata kadar salbutamol sulfat formula kontrol

Waktu (menit)	Replikasi 1	Replikasi 2	Replikasi 3	Rata-rata kadar %
30	36.20	39.80	39.80	38.60
60	50.59	55.38	56.58	54.18
90	68.57	67.37	69.77	68.57
120	78.16	80.56	82.95	80.56
150	87.75	92.54	90.15	90.15
180	94.94	96.14	100.94	97.34
210	97.34	98.54	99.74	98.54
240	93.74	93.74	97.34	94.94
270	98.54	100.94	99.74	97.34
300	93.74	92.54	94.94	93.74
330	88.95	91.35	82.95	87.75
360	80.56	82.95	81.75	81.75

## Persamaan Regresi linier waktu dan kadar

Formula	Persamaan regresi linier	r
Formula I	$Y = 19,075 + 0,0,107X$	0,975
Formula II	$Y = 13,446 + 0,0926X$	0,961
Formula III	$Y = 16,497 + 0,0892X$	0,964

**Lampiran 11. Analisis pola pelepasan salbutamol sulfat**

## a. Analisis kinetika orde nol

Waktu (menit)	% Pelepasan			
	Formula I	Formula II	Formula III	Kontrol
30	19,42	11,03	13,43	38,60
60	21,82	17,02	20,62	54,18
90	27,81	21,82	25,41	68,57
120	33,80	25,41	29,01	80,56
150	39,80	31,41	33,80	90,15
180	41,00	33,80	35,40	97,34
210	44,59	36,20	37,40	98,54
240	45,79	37,40	38,60	94,94
270	48,19	38,60	41,00	97,34
300	49,39	39,80	42,20	93,74
330	52,98	42,20	44,59	87,75
360	55,38	43,39	45,79	81,75

Persamaan regresi linier % pelepasan dan waktu

Formula	Persamaan regresi linier	r
Formula I	$Y = 19,075 + 0,0,107X$	0,975
Formula II	$Y = 13,446 + 0,0926X$	0,961
Formula III	$Y = 16,497 + 0,0892X$	0,964

b. Analisis kinetika orde satu

Waktu (menit)	Log % pelepasan			
	Formula I	Formula II	Formula III	Kontrol
30	1,29	1,04	1,13	1,59
60	1,34	1,23	1,31	1,73
90	1,44	1,34	1,41	1,84
120	1,53	1,41	1,46	1,91
150	1,60	1,50	1,53	1,95
180	1,61	1,53	1,55	1,99
210	1,65	1,56	1,57	1,99
240	1,66	1,57	1,59	1,98
270	1,68	1,59	1,61	1,99
300	1,69	1,60	1,63	1,97
330	1,72	1,63	1,65	1,94
360	1,74	1,64	1,66	1,91

Persamaan regresi linier Log % pelepasan dan waktu

Formula	Persamaan regresi linier	r
Formula I	$Y = 1,326 + 0,001 X$	0,941
Formula II	$Y = 1,171 + 0,002X$	0,904
Formula III	$Y = 1,249 + 0,001X$	0,907

## c. Analisis kinetika model higuchi

Akar waktu	% Pelepasan			
	Formula I	Formula II	Formula III	Kontrol
5.48	19,42	11,03	13,43	38,60
7.75	21,82	17,02	20,62	54,18
9.47	27,81	21,82	25,41	68,57
10.96	33,80	25,41	29,01	80,56
12.25	39,80	31,41	33,80	90,15
13.42	41,00	33,80	35,40	97,34
14.49	44,59	36,20	37,40	98,54
15.49	45,79	37,40	38,60	94,94
16.43	48,19	38,60	41,00	97,34
17.32	49,39	39,80	42,20	93,74
18.17	52,98	42,20	44,59	87,75
18.97	55,38	43,39	45,79	81,75

## Persamaan regresi linier % pelepasan dan akar waktu

Formula	Persamaan regresi linier	r
Formula I	$Y = 3,159 + 2,759X$	0,992
Formula II	$Y = -0,719 + 2,414X$	0,989
Formula III	$Y = 2,889 + 2,323X$	0,993
Kontrol		

## d. Mekanisme pelepasan Power Law

Log waktu	Log % pelepasan			
	Formula I	Formula II	Formula III	Kontrol
1.48	1,29	1,04	1,13	1,59
1.78	1,34	1,23	1,31	1,73
1.95	1,44	1,34	1,41	1,84
2.08	1,53	1,41	1,46	1,91
2.18	1,60	1,50	1,53	1,95
2.26	1,61	1,53	1,55	1,99
2.32	1,65	1,56	1,57	1,99
2.38	1,66	1,57	1,59	1,98
2.43	1,68	1,59	1,61	1,99
2.48	1,69	1,60	1,63	1,97
2.52	1,72	1,63	1,65	1,94
2.56	1,74	1,64	1,66	1,91

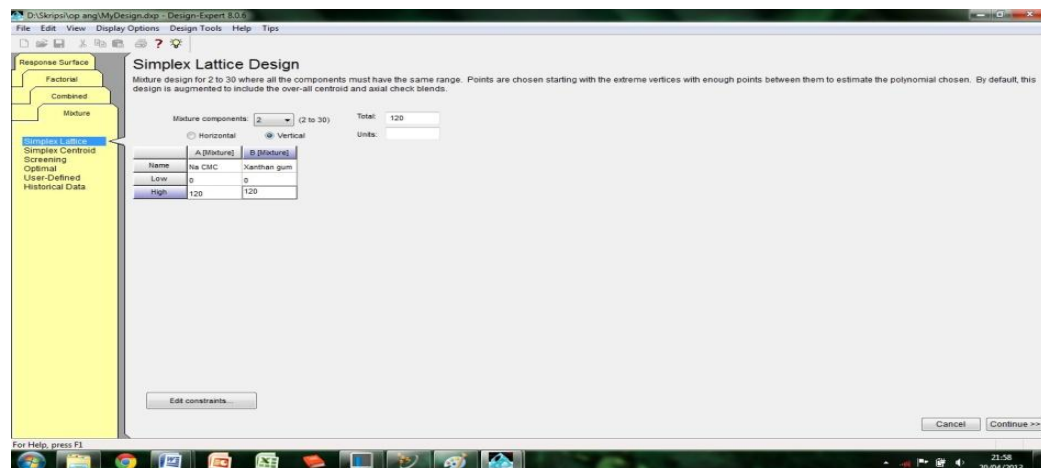
### Persamaan regresi linier Log % pelepasan dan Log waktu

Formula	Persamaan regresi linier	r
Formula I	$Y = 0,586 + 0,452X$	0,988
Formula II	$Y = 0,255 + 0,552X$	0,992
Formula III	$Y = 0,455 + 0,478X$	0,994
Kontrol		

## Lampiran 12. Penentuan formula optimum

Penentuan formula optimum

Langkah awal penggunaan aplikasi *design expert* untuk optimasi model *simplex lattice design*, pilih *mixture* → *Simplex Lattice*, tekan *Continue*

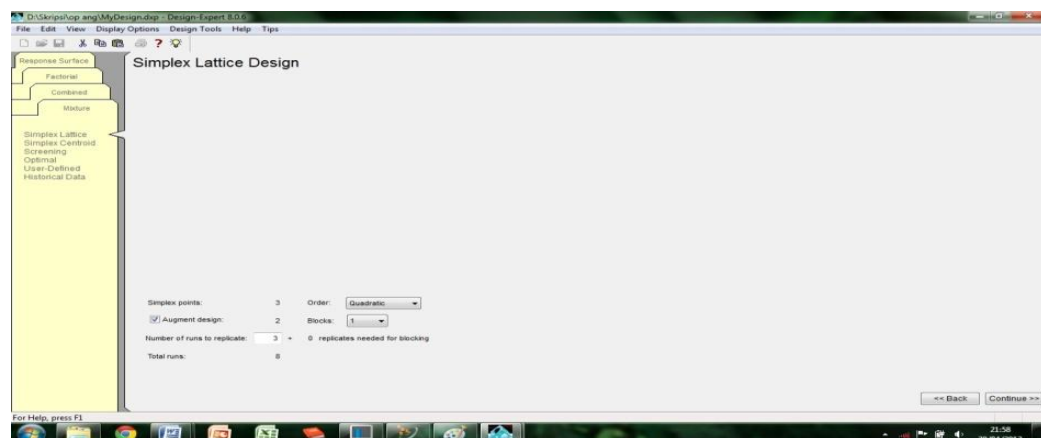


Selanjutnya isi beberapa kolom :

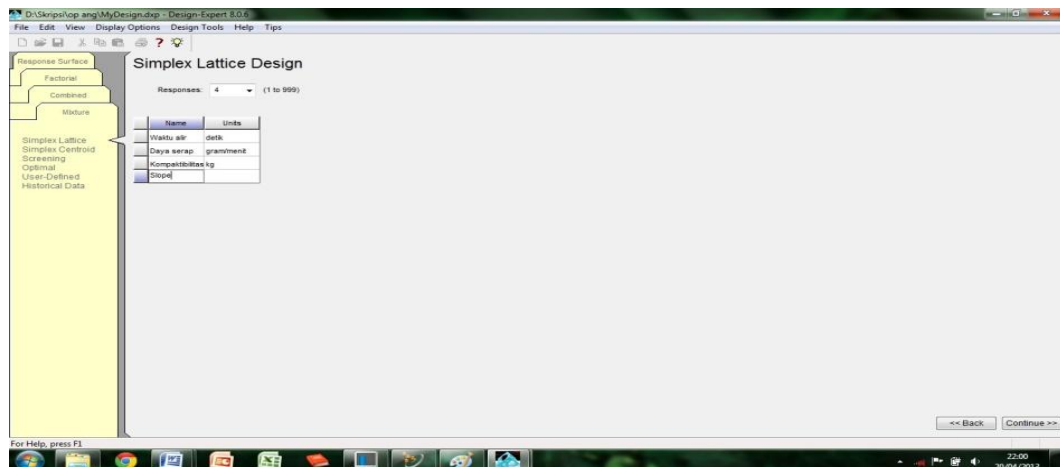
Kolom total → 120

Kolom A → formula I (Na CMC)

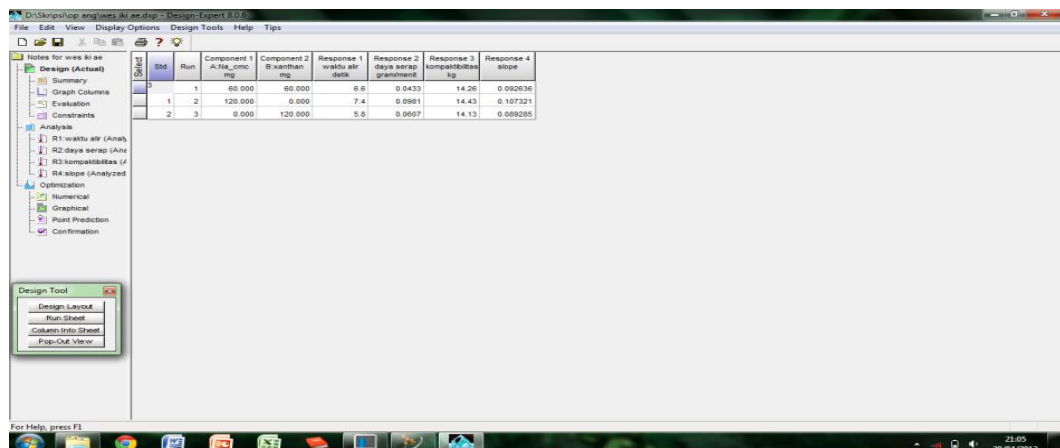
kolom B → formula II (Xanthan gum), tekan *Continue*



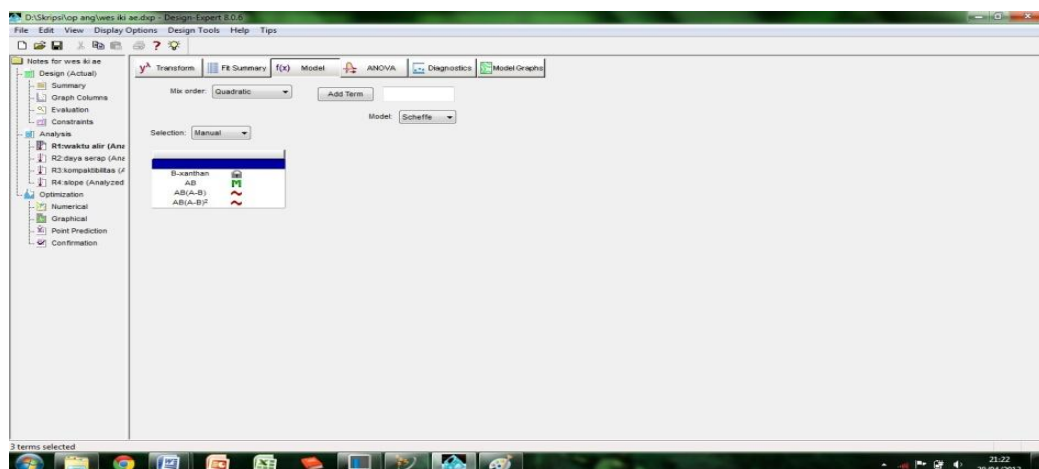
Kolom order diganti *quadratic*, selanjutnya tekan *Continue*



Kolom respon diganti angka 4 dan respon beserta satuan ditulis pada kolom yang tersedia (waktu alir, daya serap, kompaktibilitas dan slope), tekan *Continue*

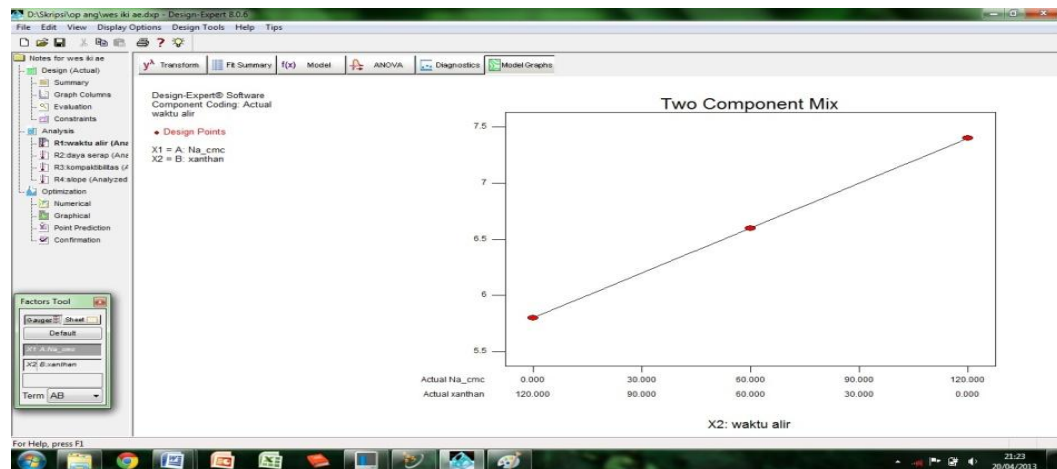


Tampilan diatas menunjukkan 3 formula dengan 4 respon yang kemudian diisi nilai respon dari ketiga formula pada masing-masing kolom

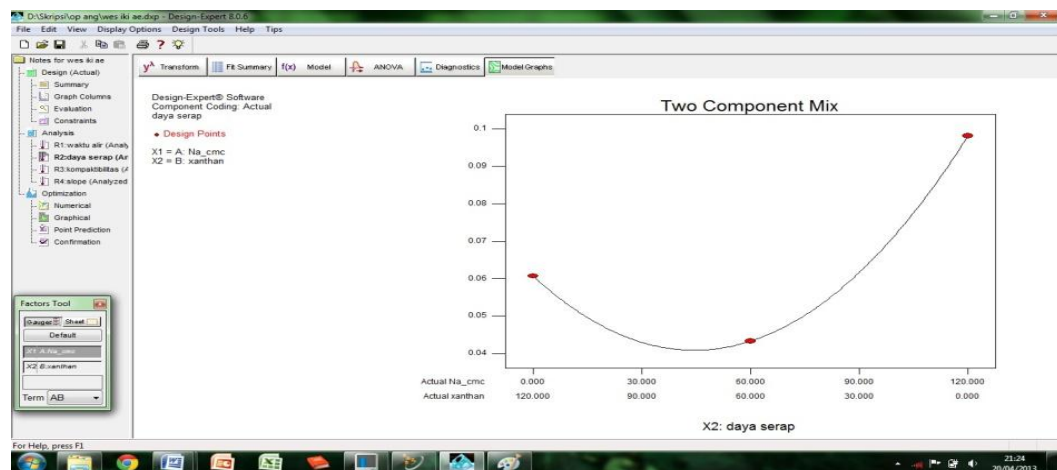


Analisis dari semua respon menggunakan model yang sama yaitu *quadratic*

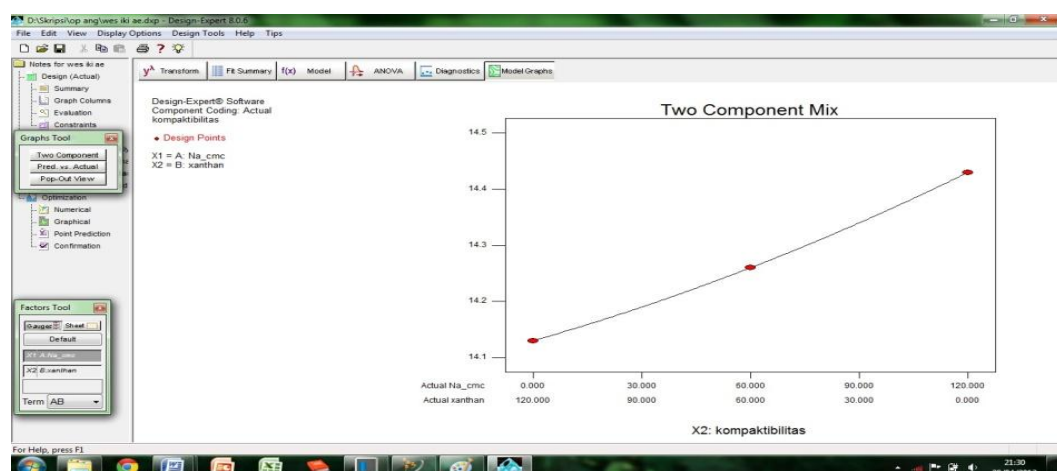




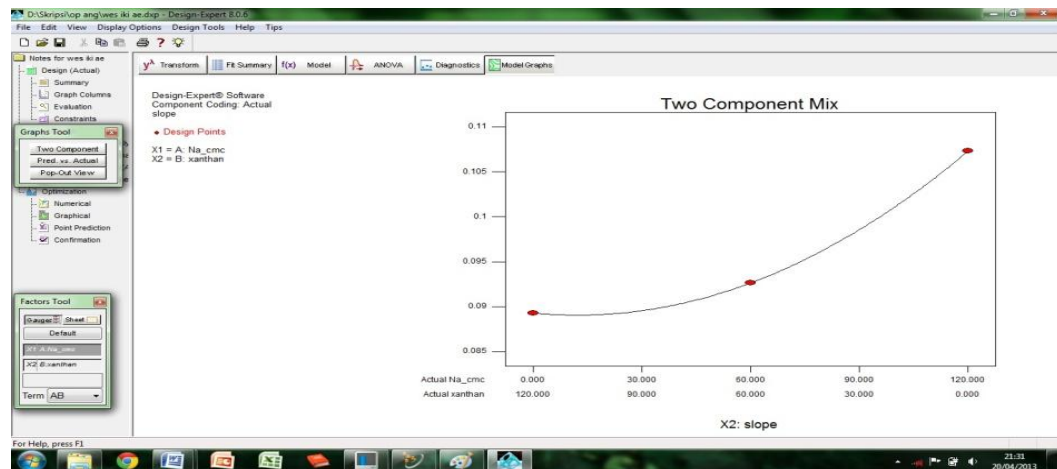
Model grafik untuk respon waktu alir



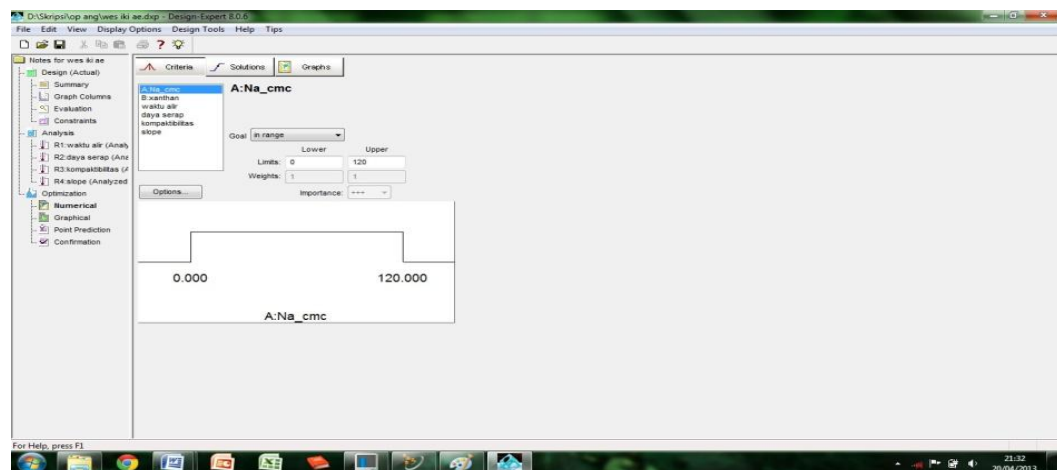
Model grafik untuk respon daya serap



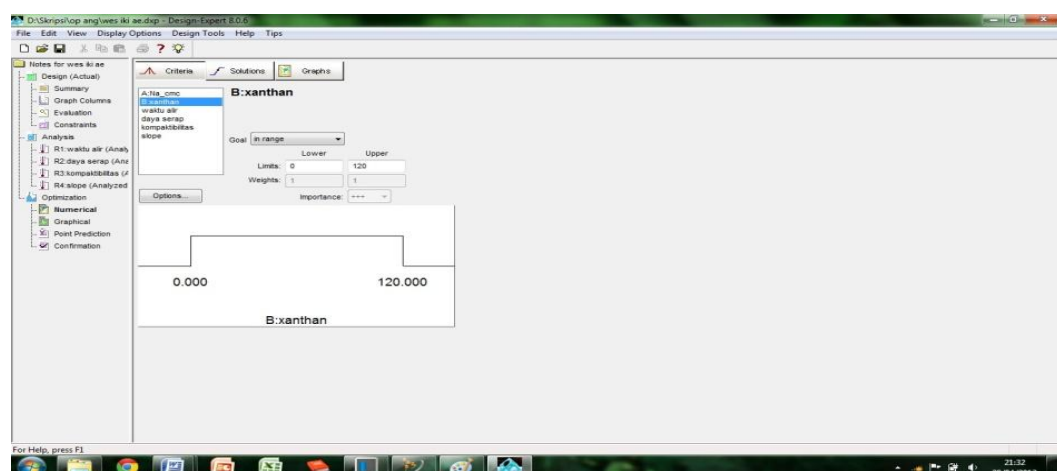
Model grafik untuk respon kompaktibilitas



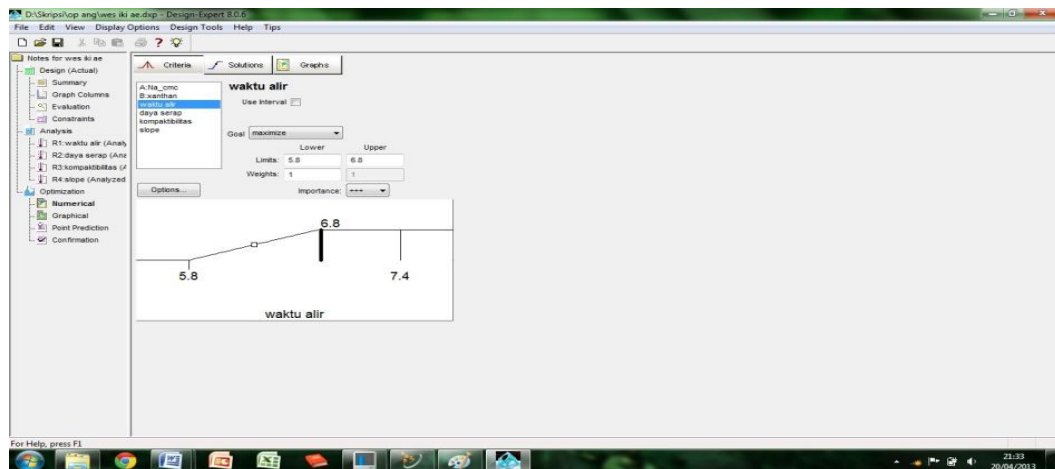
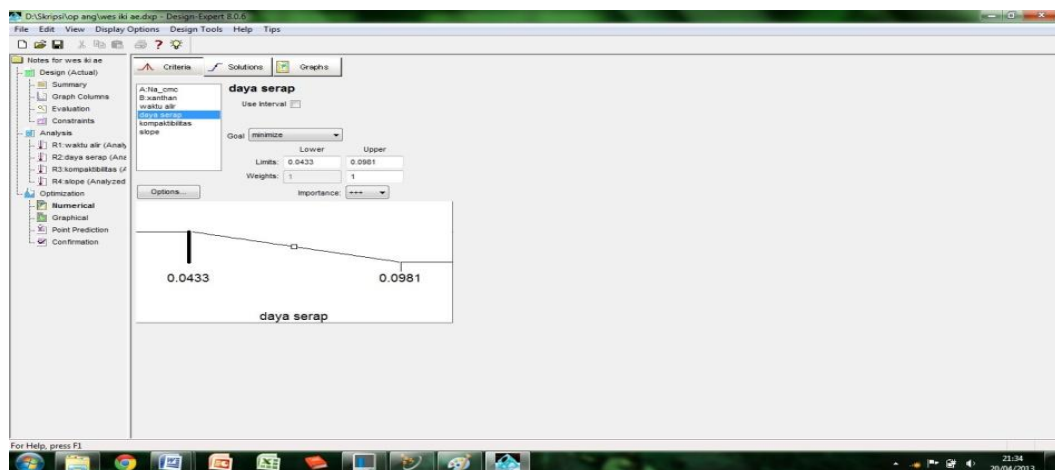
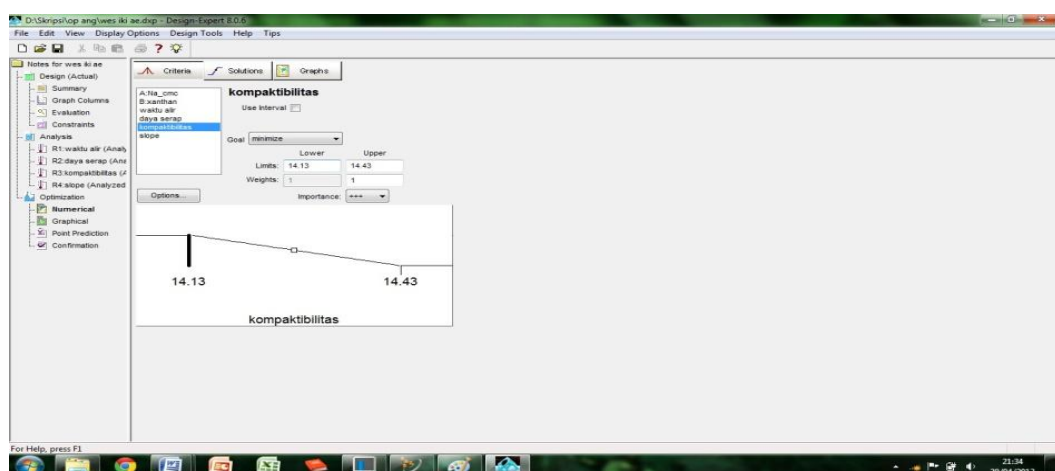
Model grafik untuk respon slope

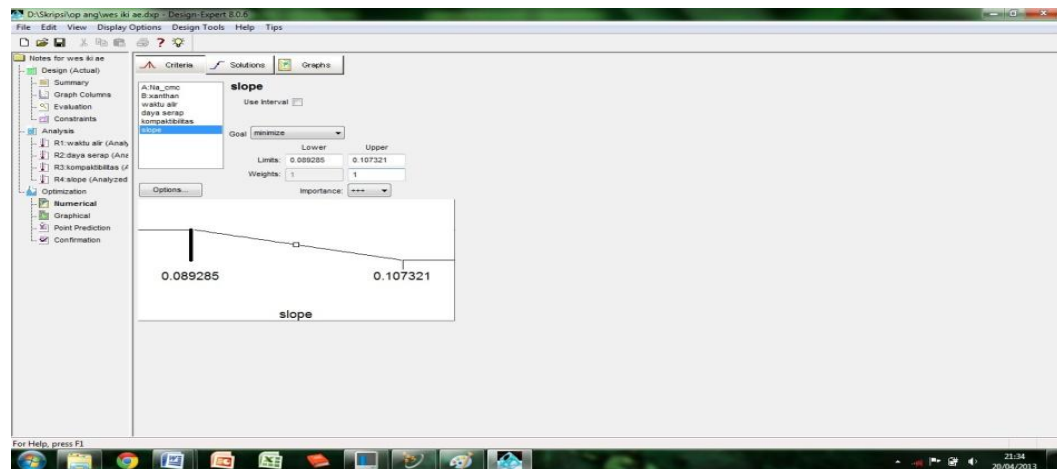


Optimasi untuk Na CMC dibuat *in range*

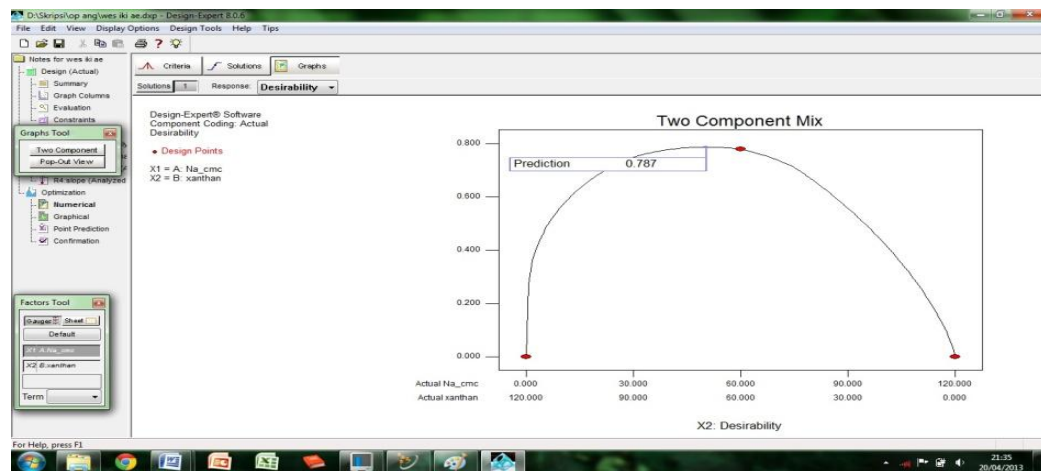


Optimasi untuk Xanthan gum dibuat *in range*

Optimasi daya serap dibuat *maximize*Optimasi untuk daya serap dibuat *minimize*Optimasi untuk kompaktilitas dibuat *minimize*



Optimasi untuk slope dibuat minimize dan semua *importance* dibuat positif 3 (+++)



### Lampiran 13. Uji sifat fisik granul dan tablet formula optimum

#### a. Waktu alir

Replikasi	Waktu (detik)
1	6,5
2	6,6
3	6,5
Rata-rata	6,53
SD	0,0577

#### b. Sudut Diam

Tinggi (cm)	Jari-jari (cm)	Sudut diam
2,23	5,20	23,21
2,29	4,95	30,35
2,62	5,26	26,51
Rata-rata		26,69
SD		3,57

## c. Kompaktibilitas

Replikasi	Kompaktibilitas (kg)
1	14,2
2	14,2
3	14,1
Rata-rata	14,12
SD	0,0577

## d. Keseragaman bobot

Tablet	Bobot (mg)
1	205
2	202
3	199
4	200
5	202
6	200
7	197
8	199
9	202
10	203
11	198
12	206
13	201
14	203
15	198
16	197
17	199
18	201
19	200
20	205
Rata-rata	200,85
SD	2,57
CV	1,24%

## e. Uji disolusi formula optimum

## Replikasi 1

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,015	0,00211	1,8990	15,8
60	0,018	0,00259	2,3306	19,4
90	0,02	0,00291	2,6183	21,8
120	0,023	0,00339	3,0499	25,4
150	0,025	0,00371	3,3376	27,8
180	0,03	0,00451	4,0569	33,8
210	0,034	0,00515	4,6324	38,6
240	0,034	0,00515	4,6324	38,6
270	0,035	0,00531	4,7762	39,8
300	0,039	0,00595	5,3517	44,6
330	0,039	0,00595	5,3517	44,6
360	0,043	0,00659	5,9271	49,4

## Replikasi 2

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,017	0,00243	2,1867	18,2
60	0,02	0,00291	2,6183	21,8
90	0,025	0,00371	3,3376	27,8
120	0,03	0,00451	4,0569	33,8
150	0,032	0,00483	4,3446	36,2
180	0,033	0,00499	4,4885	37,4
210	0,035	0,00531	4,7762	39,8
240	0,037	0,00563	5,0639	42,2
270	0,039	0,00595	5,3517	44,6
300	0,04	0,00611	5,4955	45,8
330	0,042	0,00643	5,7832	48,2
360	0,045	0,00691	6,2148	51,8

Replikasi 3

Waktu (menit)	Absorbansi	Kadar (mg/ml)	Kadar dalam 900 ml	Kadar (%)
30	0,013	0,00179	1,6113	13,4
60	0,019	0,00275	2,4744	20,6
90	0,024	0,00355	3,1937	26,6
120	0,028	0,00419	3,7692	31,4
150	0,03	0,00451	4,0569	33,8
180	0,033	0,00499	4,4885	37,4
210	0,033	0,00499	4,4885	37,4
240	0,034	0,00515	4,6324	38,6
270	0,037	0,00563	5,0639	42,2
300	0,038	0,00579	5,2078	43,4
330	0,039	0,00595	5,3517	44,6
360	0,041	0,00627	5,6394	47,0

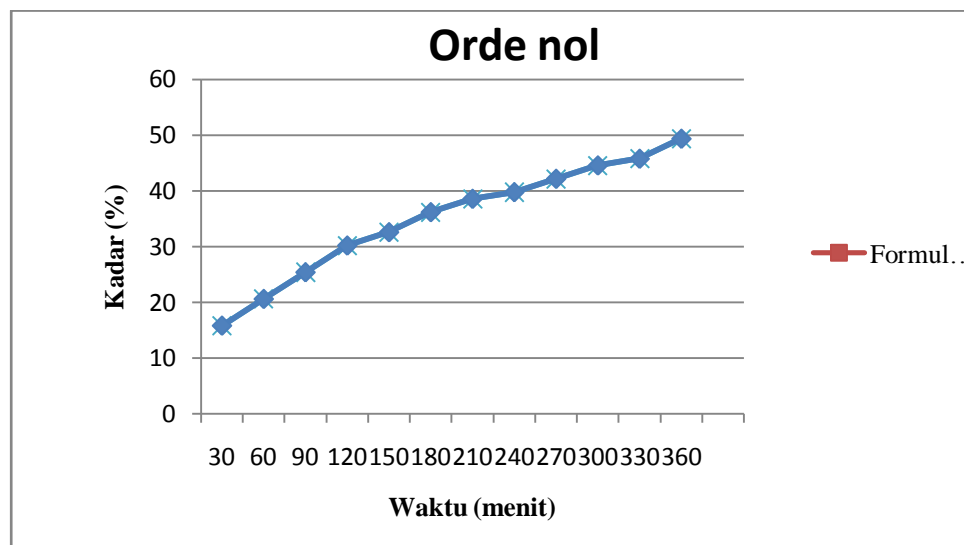
Rata-rata kadar formula optimum

Waktu (menit)	kadar (%)
30	15,8
60	20,6
90	25,4
120	30,2
150	32,6
180	36,2
210	38,6
240	39,8
270	42,2
300	44,6
330	45,8
360	49,4

### Lampiran 14. Analisis kinetika formula optimum

#### a. Analisis kinetika orde nol

Waktu (menit)	kadar (%)
30	15,8
60	20,6
90	25,4
120	30,2
150	32,6
180	36,2
210	38,6
240	39,8
270	42,2
300	44,6
330	45,8
360	49,4



Persamaan regresi linier waktu dan %pelepasan

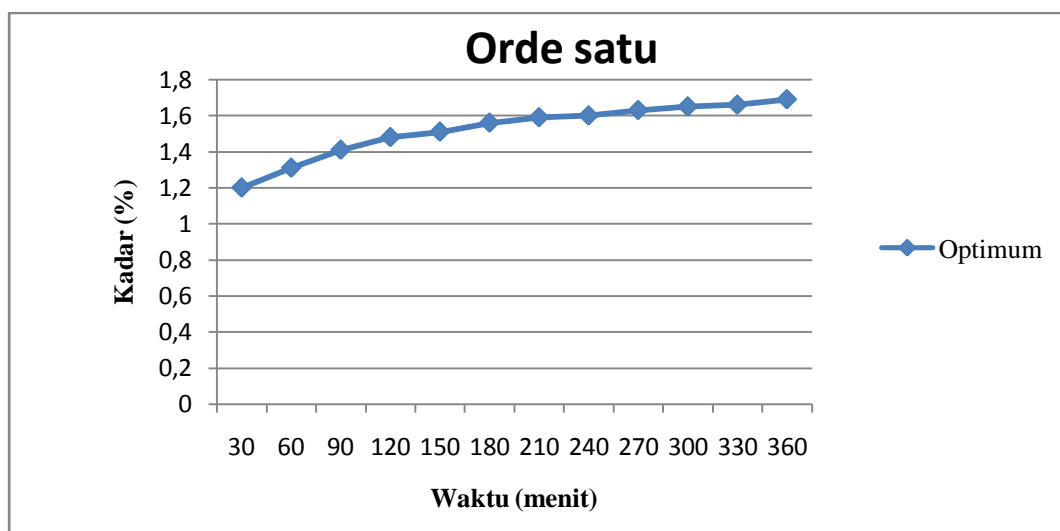
$$Y = 16,5818 + 0,0949X$$

$$R = 0,983$$



## b. Analisis kinetika orde satu

Waktu (menit)	Log Pelepasan (%)
30	1,20
60	1,31
90	1,41
120	1,48
150	1,51
180	1,56
210	1,59
240	1,60
270	1,63
300	1,65
330	1,66
360	1,69



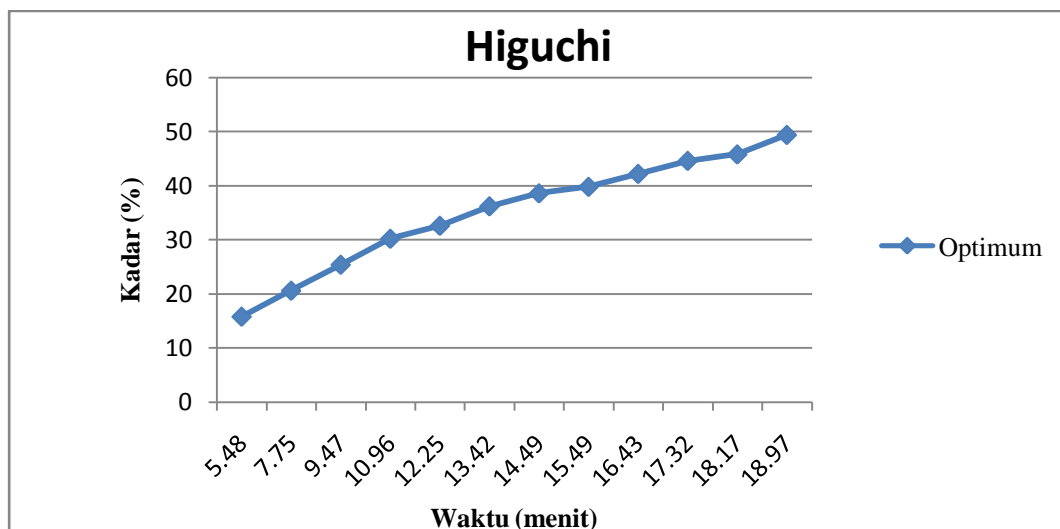
Persamaan regresi linier Log pelepasan dan waktu

$$Y = 1,267 + 0,001X$$

$$R = 0,943$$

## c. Analisis kinetika model Higuchi

Akar waktu (menit)	Pelepasan (%)
5.48	15,8
7.75	20,6
9.47	25,4
10.96	30,2
12.25	32,6
13.42	36,2
14.49	38,6
15.49	39,8
16.43	42,2
17.32	44,6
18.17	45,8
18.97	49,4



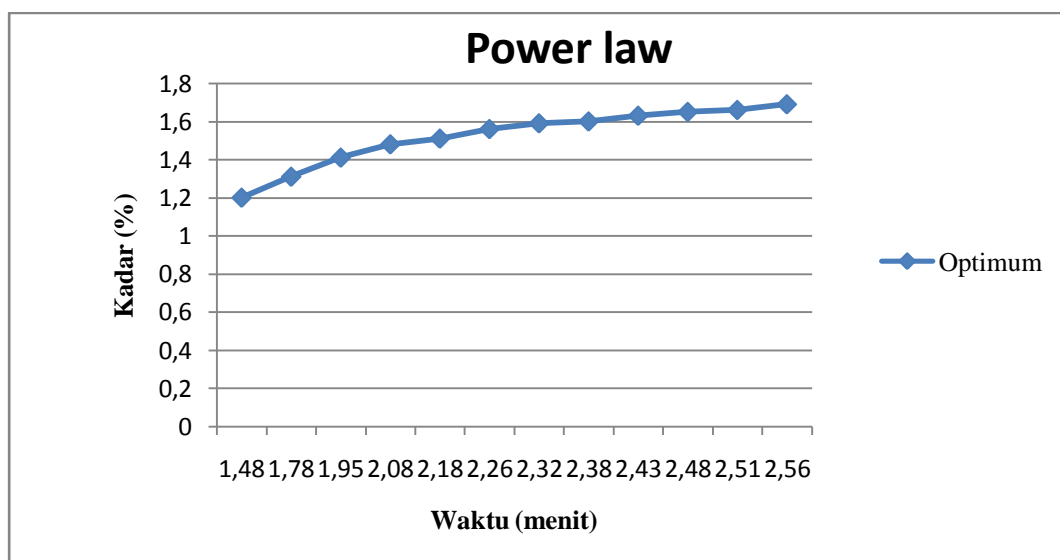
Persamaan regresi linier % Pelepasan dan akar waktu

$$Y = 2,537 + 2,439X$$

$$R = 0,998$$

## d. Mekanisme pelepasan Power Law

Log waktu (menit)	Log Pelepasan (%)
1,48	1,20
1,78	1,31
1,95	1,41
2,08	1,48
2,18	1,51
2,26	1,56
2,32	1,59
2,38	1,60
2,43	1,63
2,48	1,65
2,51	1,66
2,56	1,69



Persamaan regresi linier Log % pelepasan dan Log waktu

$$Y = 0,513 + 0,459X$$

$$R = 0,998$$

## Lampiran 15. Analisis Statistik

### a. Waktu alir

#### NPar Tests Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
waktu alir	6	6.4700	6.6000	6.501667E0	.0503653
Valid N (listwise)	6				

#### Descriptive Statistics One-Sample Kolmogorov-Smirnov Test

		waktu alir
N		6
Normal Parameters <sup>a</sup>	Mean	6.501667
	Std. Deviation	.0503653
Most Extreme Differences	Absolute	.347
	Positive	.347
	Negative	-.265
Kolmogorov-Smirnov Z		.849
Asymp. Sig. (2-tailed)		.467

a. Test distribution is Normal.

#### T-Test Group Statistics

	Formula	N	Mean	Std. Deviation	Std. Error Mean
waktu alir	prediksi	3	6.470000	.0000000	.0000000
	percobaan	3	6.533333	.0577350	.0333333

## Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
waktu alir	Equal variances assumed	16.000	.016	-1.900	4	.130	-.06333	.03333	-.15588	.0292148
	Equal variances not assumed			-1.900	2.000	.198	-.06333	.03333	-.20675	.0800884

## b. Daya serap

Descriptives  
Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Daya serap	6	.03935	.04123	.0406728	.00083715
Valid N (listwise)	6				

NPar Tests  
One-Sample Kolmogorov-Smirnov Test

		Daya serap
N		6
Normal Parameters <sup>a</sup>	Mean	.0406728
	Std. Deviation	.00083715
Most Extreme Differences	Absolute	.374
	Positive	.255
	Negative	-.374
Kolmogorov-Smirnov Z		.917
Asymp. Sig. (2-tailed)		.370

a. Test distribution is Normal.

T-Test  
Group Statistics

	Formula	N	Mean	Std. Deviation	Std. Error Mean
Daya serap	prediksi	3	.0412256	.00000000	.00000000
	percobaan	3	.0401200	.00091395	.00052767

## Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Daya serap	Equal variances assumed	8.762	.042	2.095	4	.104	.00110560	.00052767	-.00035944	.0025706
	Equal variances not assumed			2.095	2.000	.171	.00110560	.00052767	-.00116477	.0033759

## c. Kompaktibilitas

Descriptives  
Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Kompaktibilitas	6	14.10	14.24	14.2015	.05284
Valid N (listwise)	6				

NPar Tests  
One-Sample Kolmogorov-Smirnov Test

		Kompaktibilitas
N		6
Normal Parameters <sup>a</sup>	Mean	14.2015
	Std. Deviation	.05284
Most Extreme Differences	Absolute	.322
	Positive	.255
	Negative	-.322
Kolmogorov-Smirnov Z		.788
Asymp. Sig. (2-tailed)		.564

a. Test distribution is Normal.

**T-Test  
Group Statistics**

Formula	N	Mean	Std. Deviation	Std. Error Mean
Kompaktibilitas pecobaan	3	14.2364	.00000	.00000
prediksi	3	14.1667	.05774	.03333

**Independent Samples Test**

	Levene's Test for Equality of Variances		t-test for Equality of Means							
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		
								Lower	Upper	
Kompaktibilitas	Equal variances assumed	16.000	.016	2.092	4	.105	.06973	.03333	-.02281	.16228
	Equal variances not assumed			2.092	2.000	.172	.06973	.03333	-.07369	.21316

**d. Disolusi**

**Descriptive Statistics**

	N	Minimum	Maximum	Mean	Std. Deviation
Slope	6	.0899	.1008	.093148	.0040090
Valid N (listwise)	6				

**NPar Tests**

**One-Sample Kolmogorov-Smirnov Test**

		Slope
N		6
Normal Parameters <sup>a</sup>	Mean	.093148
	Std. Deviation	.0040090
Most Extreme Differences	Absolute	.341
	Positive	.341
	Negative	-.211
Kolmogorov-Smirnov Z		.836
Asymp. Sig. (2-tailed)		.486

a. Test distribution is Normal.

T-Test  
Group Statistics

Formula	N	Mean	Std. Deviation	Std. Error Mean
Slope prediksi	3	.091332	.0000000	.0000000
percobaan	3	.094965	.0055028	.0031770

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Slope	Equal variances assumed	6.324	.066	-1.144	4	.317	-.0036331	.0031770	-.0124539	.0051878
	Equal variances not assumed			-1.144	2.000	.371	-.0036331	.0031770	-.0173027	.0100365



# CERTIFICATE OF ANALYSIS

## Cipla

BATCH NO. : SS/117/10-11 ✓ A. R. NO. : PR10090098 Qty. : 1 x 25 kgs	<b>SALBUTAMOL SULPHATE</b>	MFG. DT. : 24/08/2010 ✓ EXP. DT. : 23/07/2015 ✓
<b>TEST</b>	<b>STANDARD</b>	<b>RESULT</b>
<b>DESCRIPTION</b>	White or almost white, crystalline powder.	Meets the requirement
<b>SOLUBILITY</b>	Freely soluble in water, practically insoluble or very slightly soluble in ethanol (96 %) and in methylene chloride.	Meets the requirement
<b>IDENTIFICATION</b>	<b>B)</b> The infrared spectrum of the sample is concordant with the spectrum obtained with salbutamol sulphate CRS.  <b>E)</b> It gives reaction (a) of sulphates.	Meets the requirement
<b>APPEARANCE OF SOLUTION</b>	Solution S is clear and not more intensely coloured than reference solution BY <sub>6</sub> .	Meets the requirement
<b>OPTICAL ROTATION (°)</b>	-0.100 to +0.100.	Nil
<b>ACIDITY OR ALKALINITY</b>	Not more than 0.4 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.	Meets the requirement
<b>IMPURITY J (%)</b>	NMT 0.20	0.01
<b>RELATED SUBSTANCES (%)</b>		Meets the requirement
Impurity A	NMT 0.30	Not detected
Impurity B	NMT 0.30	0.18
Impurity C	NMT 0.30	0.22
Impurity D	NMT 0.30	0.09
Impurity E	NMT 0.30	Not detected
Impurity F	NMT 0.30	0.05
Impurity G	NMT 0.30	Not detected
Impurity H	NMT 0.30	Not detected
Impurity I	NMT 0.30	Not detected
Total impurities	NMT 1.00	0.54
<b>BORON (ppm)</b>	NMT 50	Meets the requirement
<b>LOSS ON DRYING (%)</b>	NMT 0.50	0.06
<b>SULPHATED ASH (%)</b>	NMT 0.10	0.02
<b>ASSAY (%)</b> C <sub>12</sub> H <sub>14</sub> N <sub>2</sub> O <sub>10</sub> S, (dried substance)	NLT 98.0      NMT 101.0	Meets the requirement 100.8
<b>DATE OF ANALYSIS : 15.09.2010</b>		
<b>REMARK : COMPLIES WITH BP'2010 STANDARD</b>		
QUALITY CONTROL : <i>P. Jay</i> DATE : 20.09.2010	QUALITY ASSURANCE : <i>Alada</i> DATE : 20.09.2010	

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