

## **BAB V**

### **KESIMPULAN DAN SARAN**

#### **A. Kesimpulan**

1. Kombinasi *superdisintegrant sodium starch glycolate* dan *filler-binder ludipress®* berpengaruh terhadap mutu fisik dan profil disolusi pada sediaan FDT metoklopramid HCl dengan konsentrasi *sodium starch glycolate* yang rendah dan *ludipress®* yang tinggi meningkatkan kekerasan, menurunkan kerapuhan, mempercepat waktu hancur, dan meningkatkan profil disolusi ( $Q_3$  dan  $DE_3$ ).
2. Komposisi optimum kombinasi *sodium starch glycolate* yaitu pada konsentrasi 2% (3 mg) dan *ludipress®* 58% (87 mg) dalam sediaan FDT metoklopramid terhadap parameter kritis kekerasan, kerapuhan, waktu hancur, dan profil disolusi ( $Q_3$  dan  $DE_3$ ).

#### **B. Saran**

1. Perlu dilakukan penelitian lebih lanjut dalam formula FDT metoklopramid HCl dengan menggunakan *superdisintegrant* dan *filler-binder* lainnya untuk menghasilkan formula tablet dengan waktu disintegrasi yang lebih cepat.
2. Perlu dilakukan metode optimasi formula yang berbeda dalam menganalisis sifat fisik tablet FDT.

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## Lampiran 1. Sertifikat analisis metoklopramid HCl

		37.8.6 Test result Report (mdf)*										
		PHAPROS, PT				Date: 25/07/19						
Quality Order	Batch	Item Number	Insp Loc	Location	Procedure	Qty Pending	Qty Accepted	Qty Rejected	Order Date	Due Date	Eff Date	St
BB.17/0308	2089	14313102 METOCLOPRAMIDE HCL	PM	gbb	Pemeriksaan BB/BK	20.0	20.0	0.0	06/04/17	14/04/17	10/04/17	c
Op Number	Characteristic	Actual Results	Specification			Measure	Pass					
100_01	PEMERIKAN	sesuai	‡			PERSEN	yes					
02	KELARUTAN	sesuai	‡			PERSEN	yes					
03	IDENTIFIKASI	sesuai	‡			PERSEN	yes					
04	KADAR AIR	5,326	4,5 <sup>+</sup> 5,5			PPM	yes					
05	KEMURNIAN KROMATOGRAFI	sesuai	SESUAI			PERSEN	yes					
06	LOGAM BERAT <20	20	<=20			PPM	yes					
07	KEJERNIHAN & WARNA	sesuai	SESUAI			PERSEN	yes					
08	ABU SULFAT	0	<=0.1			PERSEN	yes					
09	KACAR	99,5	99,0 <sup>+</sup> 101,0			PERSEN	yes					
101	PETUGAS SAMPLING	san	‡			PERSEN	yes					
102	PEMERIKSA	an,av	‡			PERSEN	yes					
103	CATATAN	-	‡			PERSEN	yes					

**Lampiran 2. Sertifikat analisis sodium starch glycolate**



**Certificate Of Analysis**

Item Number	S1962	Lot Number	IHE0090
Item	Sodium Starch Glycolate, pH 5.5-7.5, Type A, NF		
CAS Number	9063-38-1		
Molecular Formula		Molecular Weight	

Test	Specification		Result
	min	max	
SODIUM (Na; ALCOHOL-WASHED, DRIED BASIS)	2.8	4.2%	3.0 %
pH (1g in 30ml of Water)	5.5	7.5	5.8
MICROBIAL LIMITS	TO PASS TEST		PASSES TEST
LOSS ON DRYING		10.0%	7.2 %
IRON (Fe)		0.002%	<0.002 %
SODIUM CHLORIDE		7.0 %	4.1 %
SODIUM GLYCOLATE		2.0%	<2.0 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			30-NOV-2019
DATE OF MANUFACTURE			23-DEC-2017
APPEARANCE			WHITE FREE FLOWING POWDER
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



Certificate of Analysis Results Certified By:

Adan Hernandez  
Quality Control Manager  
Spectrum Chemicals & Laboratory Products

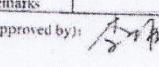
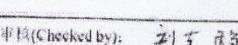
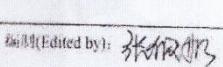
All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

### Lampiran 3. Sertifikat analisis *ludipress*<sup>®</sup>

<b>BASF</b> We create chemistry		<b>Certificate of Analysis</b>																													
BASF SE																															
<small>Please note that the certificates of analysis are also conveniently available online and around the clock at <a href="http://www.worldaccount.bASF.com">www.worldaccount.bASF.com</a></small>																															
Fax No 0062215262541																															
<b>PT. BASF INDONESIA</b> JL. PROF. DR. SATRIO, KAV. 3-5 12940 Jakarta Indonesia		2018-10-12 ENO/QA Hr. Dr. Florian Wildschek florian.wildschek@bASF.com Certificate No 5231 Page 1 of 3																													
<b>Inspection Certificate 3.1 according to EN 10204</b>																															
Ludipress® 1KG Plastic bottle Purchase Order/Customer Product# 4946995595 00000000050015498		Material 50015498 Order 3015046792 000010 Delivery 3190910640 000010 Lot 13781024U0 Lot/Qty 2.000 KG Total 2.000 KG																													
<table border="1"> <thead> <tr> <th>Test Parameter</th> <th>Requirements</th> <th>UoM</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td>white, freeflowing powder</td> <td></td> <td>conforms</td> </tr> <tr> <td>Soluble PVP (photometr.)</td> <td>Min.: 3.0 Max.: 4.0</td> <td>g/100g</td> <td>3.8</td> </tr> <tr> <td>Insoluble PVP (gravimetr.)</td> <td>Min.: 3.0 Max.: 4.0</td> <td>g/100g</td> <td>3.3</td> </tr> <tr> <td>Water (Karl-Fischer-Titr.)</td> <td>Max.: 6.0</td> <td>g/100g</td> <td>5.7</td> </tr> <tr> <td>Heavy Metals</td> <td>Max.: 10</td> <td>mg/kg</td> <td>max. 10</td> </tr> <tr> <td>Lactose Monohydrate (polarim.)</td> <td>Min.: 91.1 Max.: 94.9</td> <td>g/100g</td> <td>92.8</td> </tr> </tbody> </table>				Test Parameter	Requirements	UoM	Results	Appearance	white, freeflowing powder		conforms	Soluble PVP (photometr.)	Min.: 3.0 Max.: 4.0	g/100g	3.8	Insoluble PVP (gravimetr.)	Min.: 3.0 Max.: 4.0	g/100g	3.3	Water (Karl-Fischer-Titr.)	Max.: 6.0	g/100g	5.7	Heavy Metals	Max.: 10	mg/kg	max. 10	Lactose Monohydrate (polarim.)	Min.: 91.1 Max.: 94.9	g/100g	92.8
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<small>The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.</small>																															
<small>This is a computer-generated document. No signature is required.</small>																															

## Lampiran 4. Sertifikat analisis manitol

地址: 青岛市黄岛区明月路777号 记录编号: 09SM02027-R06(02)		邮编: 266400			
 明月 <b>青岛明月海藻集团有限公司</b> <b>甘露醇检验报告</b> <b>QINGDAO BRIGHT MOON SEAWEED GROUP CO.,LTD</b> <b>MANNITOL INSPECTION REPORT</b>					
产品名称 Product Name	甘露醇 MANNITOL	产品规格 Specifications	药用辅料 (Pharmaceutical excipients)		
生产批号 Batch No.	H361812023	批量, kg Quantity	15000		
包装规格 Packing Size	20KG/纸板桶/bag drums/bags	生产日期 Production Date	12/24/2018		
检验日期 Test Date	12/28/2018	有效期 Valid Date	12/23/2021		
性状, Characters	白色结晶性粉末,无臭,味甜,White crystalline powder,odorless;taste,sweetish.				
检测结果 Test Result	项目 (Item)	标准要求 (Standard)	检测结果 (Test Result)	检测依据 (Testing grounds)	单项判定 (Individual decision)
	鉴别(Identification)	Be consistent with the refer	Be consistent with the refer	USP41	qualified
	澄清度与颜色(Clarity&Colour)	Clear and Colorless	Clear and Colorless	USP41	qualified
	干基失重(Loss On Drying), %	≤0.5	0.040	USP41	qualified
	镍(Nickel), ppm	≤1.0	未检出 (LOD=0.036)	USP41	qualified
	山梨糖醇(Sorbitol), %	≤2.0	0.04	USP41	qualified
	麦芽糖醇和异麦芽糖醇(Maltitol and Isomalt), %	≤2.0	0.02	USP41	qualified
	不確定杂质, % (Unspecified impurities)	≤0.1	0.074	USP41	qualified
	总杂质(Total impurities), %	≤2.0	0.13	USP41	qualified
	含量(Assay), %	97.0-102.0	99.80	USP41	qualified
	熔点(Melting Point), °C	165.0-170.0	166.5-167.5	USP41	qualified
	还原糖(Reducing Sugar), %	≤0.1	≤0.1	USP41	qualified
	电导率(Conductivity), μS/cm	≤20	1.45	USP41	qualified
需氧菌总数(Total aerobic bacteria), CFU/g	≤1000	≤10	USP41	qualified	
霉菌和酵母菌(Mold and yeast), CFU/g	≤100	≤10	USP41	qualified	
大肠杆菌(Escherichia coli)	Negative	Negative	USP41	qualified	
日期 Date	检验报告出具日期: 2019.01.04 签发日期(Issue date): 2019.01.04 检验报告专用章(Seal)				
备注 Remarks					
批准(Approved by): 	审核(Checked by): 	编辑(Edited by): 			

### Lampiran 5. Pemeriksaan sifat serbuk tablet

a. Waktu alir

Replikasi	Waktu alir		
	formula 1	formula 2	formula 3
1	0.71	0.75	0.79
2	0.72	0.75	0.8
3	0.71	0.76	0.78
rata-rata	0.71	0.75	0.79
SD	0.005774	0.005774	0.01

b. Sudut diam

Formula 1	Tinggi	Diameter	Sudut Diam
	2.15	8.5	26.83
	2.13	8.5	26.62
	2.1	8.3	26.84
Rata-rata	2.13	8.43	26.76
SD			0.13

Formula 2	Tinggi	Diameter	Sudut Diam
	2.21	8.15	28.47
	2.2	8.2	28.22
	2.18	8.18	28.06
Rata-rata	2.20	8.18	28.25
SD			0.21

Formula 3	Tinggi	Diameter	Sudut Diam
	2.28	7.8	30.31
	2.25	7.75	30.14
	2.3	7.85	30.37
Rata-rata	2.28	7.8	30.27
SD			0.12

- Contoh perhitungan (formula 1 replikasi 1) :

$$\tan \Theta = h/r$$

$$\tan \Theta = 2.15/4.25$$

$$\tan \Theta = 0.5059$$

$$\Theta = 26.83$$

Keterangan :

$\Theta$  : sudut diam

$h$  : tinggi tumpukan serbuk

$r$  : jari-jari serbuk

c. *Bulk density, tapperd density, hausner ratio, dan carr's index*

Formula 1				
Bobot Serbuk (mg)	bulk density (g/mL)	Tapped Density (g/mL)	hausner ratio (g/mL)	carr's index (%)
22.567	0.68	0.75	1.103	9.33
22.565	0.7	0.78	1.114	10.26
22.560	0.7	0.78	1.114	10.26
Rata-rata	0.69	0.77	1.111	9.95
SD	0.012	0.017	0.007	0.53

Formula 2				
Bobot Serbuk (mg)	Bulk density (g/mL)	Tapped density (g/mL)	Hausner ratio (g/mL)	Carr's index (%)
19.462	0.78	0.85	1.090	8.24
19.460	0.78	0.85	1.090	8.24
19.457	0.81	0.88	1.086	7.95
Rata-rata	0.79	0.86	1.089	8.14
SD	0.017	0.017	0.002	0.16

<b>Formula 3</b>				
Bobot Serbuk (mg)	Bulk density (g/mL)	Tapped density (g/mL)	Hausner ratio	Carr's index (%)
21.06	0.7	0.75	1.071	6.67
21.021	0.7	0.78	1.114	10.26
20.010	0.69	0.74	1.072	6.76
Rata-rata	0.70	0.76	1.086	7.89
SD	0.006	0.021	0.024	2.05

Contoh perhitungan (formula 1 replikasi 1) :

- Bulk density

$$P_b = M / V_b$$

$$P_b = 22.567 / 33$$

$$P_b = 0.68$$

Keterangan :

P<sub>b</sub> : bulk density

M : bobot serbuk

V<sub>b</sub> : Volume bulk

- Tapped density

$$C = M / V_t$$

$$D_t = 22.567 / 30$$

$$D_t = 0.75$$

Keterangan :

D<sub>t</sub> : tapped density

M : massa

V<sub>t</sub> : volume serbuk setelah tapped

- Hausner ratio

$$\begin{aligned} \text{Hausner ratio} &= \frac{\text{Tapped Volume}}{\text{Bulk Density}} \\ &= \frac{0.75}{0.68} = 1.103 \end{aligned}$$

- Carr's index

$$\begin{aligned} \text{Carr's index} &= 100\% \times \frac{\text{Tapped Volume} - \text{bulk density}}{\text{Tapped Density}} \\ &= 100\% \times \frac{0.75 - 0.68}{0.75} \\ &= 9.33\% \end{aligned}$$

### Lampiran 6. Kekerasan tablet

a. Hasil data

Replikasi	Run	Formula		
		FI	FII	FIII
<b>1</b>	1	3.95	3.86	3.85
	2	3.87	3.99	3.81
	3	3.83	3.72	3.73
	4	3.71	3.81	3.79
	5	3.73	3.88	3.85
	6	3.78	3.92	3.9
	7	3.9	3.64	3.69
	8	4.08	3.72	3.71
	9	3.75	3.9	3.65
	10	4.15	3.73	3.7
<b>2</b>	1	3.87	3.77	3.68
	2	3.83	3.96	3.85
	3	3.76	3.69	3.67
	4	3.81	3.75	3.81
	5	3.76	3.82	3.8
	6	3.79	3.9	3.78
	7	3.85	3.7	3.89
	8	3.73	3.71	3.75
	9	3.77	3.96	3.65
	10	4.11	3.85	3.7
<b>3</b>	1	3.86	3.75	3.873
	2	4.02	3.9	3.81
	3	3.91	3.73	3.86
	4	3.83	3.79	3.79
	5	3.67	3.73	3.85
	6	3.81	3.88	3.9
	7	3.78	3.9	3.71
	8	3.82	3.75	3.71
	9	3.7	3.95	3.77
	10	4.11	3.84	3.7
Rata-rata		3.851333	3.81666	3.774433
SD		0.128459	0.09625	0.078635

b. Perhitungan *simplex lattice design*

- $A = 0$   
 $B = 1$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$3.85 = a(0) + b(1) + ab(0)(1)$$

$$b = 3.85$$

- $A = 1$

$$B = 0$$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$3.77 = a(1) + b(0) + ab(1)(0)$$

$$a = 3.77$$

- $A = 0.5$

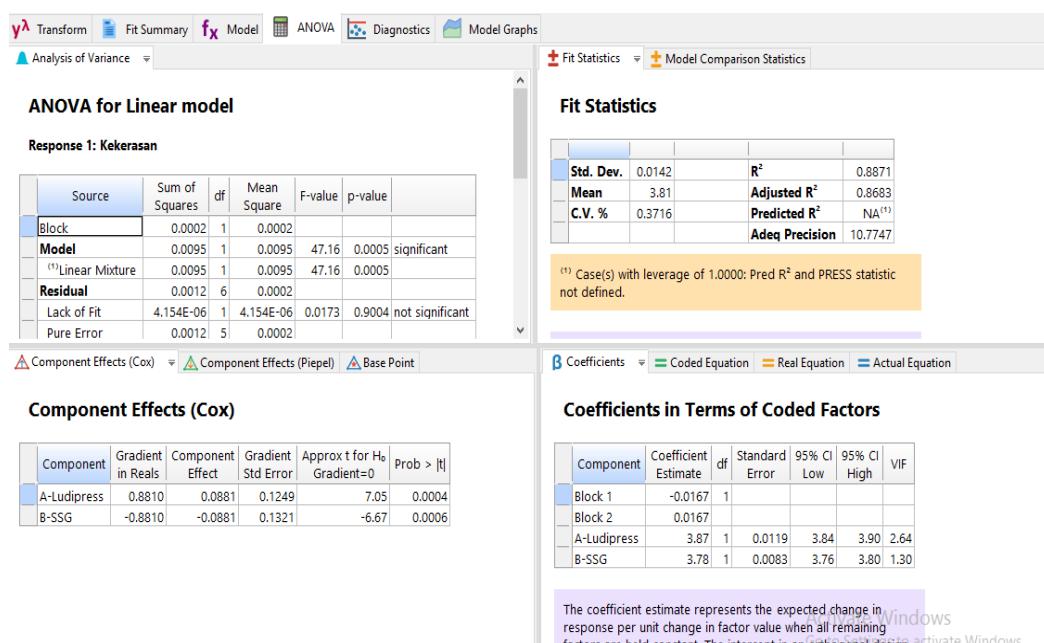
$$B = 0.5$$

$$Y = a(0.5) + b(0.5) + ab(A)(B)$$

$$3.82 = 3.85(0.5) + 3.77(0.5) + ab(0.5)(0.5)$$

$$ab = 0.04$$

c. Hasil ANOVA *simplex lattice design*



### Lampiran 7. Kerapuhan tablet

#### a. Hasil data

Formula 1			
Replikasi	Sebelum	Sesudah	% Kerapuhan
1	3.5575	3.5241	0.9388
2	3.5612	3.5272	0.9547
3	3.5891	3.555	0.9500
Rata-rata			0.9478
SD			0.008

Formula 2			
Replikasi	Sebelum	Sesudah	% Kerapuhan
1	3.5574	3.5229	0.9698
2	3.5663	3.5319	0.9645
3	3.5942	3.5592	0.9737
Rata-rata			0.9693
SD			0.004

Formula 3			
Replikasi	Sebelum	Sesudah	%kerapuhan
1	3.5571	3.5220	0.9867
2	3.5624	3.5270	0.9937
3	3.5888	3.5549	0.9446
Rata-rata			0.9750
SD			0.026

Contoh perhitungan % kerapuhan (formula 1 replikasi 1)

$$F = \frac{(W_{initial}) - (W_{final})}{(W_{initial})} \times 100$$

$$F = \frac{(3.5575) - (3.5241)}{(3.5575)} \times 100$$

$$F = 0.9388 \%$$

Keterangan :

$F$  = kerapuhan tablet

$W_{o\ initial}$  = bobot mula-mula

$W_{o\ final}$  = bobot setelah pengujian

b. Perhitungan *simplex lattice design*

- $A = 0$
- $B = 1$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$0.943 = a(0) + b(1) + ab(0)(1)$$

$$b = 0.948$$

- $A = 1$

$$B = 0$$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$0.970 = a(1) + b(0) + ab(1)(0)$$

$$a = 0.970$$

- $A = 0.5$

$$B = 0.5$$

$$Y = a(0.5) + b(0.5) + ab(A)(B)$$

$$0.969 = 0.943(0.5) + 0.970(0.5) + ab(0.5)(0.5)$$

$$ab = 0.05$$

### c. Hasil ANOVA

Screenshot of SPSS software showing ANOVA results and other statistical outputs.

**Response 2: Kerapuhan**

Source	Sum of Squares	df	Mean Square	F-value	p-value
Block	0.0005	1	0.0005		
<b>Model</b>	0.0018	1	0.0018	58.59	0.0003 significant
( <sup>a</sup> )Linear Mixture	0.0018	1	0.0018	58.59	0.0003
<b>Residual</b>	0.0002	6	0.0000		
Lack of Fit	1.282E-06	1	1.282E-06	0.0350	0.8590 not significant
Pure Error	0.0002	5	0.0000		
<b>Cor Total</b>	0.0025	8			

**Fit Statistics**

	R <sup>2</sup>	Adeq Precision
Std. Dev.	0.0055	0.9071
Mean	0.9611	0.8916
C.V. %	0.5771	NA <sup>(1)</sup>
Predicted R <sup>2</sup>		
Adeq Precision	14.1713	

<sup>(1)</sup> Case(s) with leverage of 1.0000: Pred R<sup>2</sup> and PRESS statistic not defined.

**Component Effects (Cox)**

Component	Gradient in Reals	Component Effect	Gradient Std Error	Approx t for H <sub>0</sub> : Gradient=0	Prob >  t
A-Ludipress	-0.3846	-0.0385	0.0489	-7.86	0.0002
B-SSG	0.3846	0.0385	0.0517	7.43	0.0003

**Coefficients in Terms of Coded Factors**

Component	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Block 1	0.0227	1				
Block 2	-0.0227					
A-Ludipress	0.9242	1	0.0047	0.9128	0.9356	2.64
B-SSG	0.9627	1	0.0033	0.9547	0.9707	1.30

The coefficient estimate represents the expected change in response per unit change in factor value when all remaining factors are held constant. The intercept in an orthogonal design activate Windows Winc

### Lampiran 8. Waktu hancur

a. Hasil data

Replikasi	Waktu hancur (detik)		
	F1	F2	F3
R1	32.16	38.55	46.04
R2	34.23	40.11	43.62
R3	30.46	36.3	48.19
Rata-rata	32.28	38.32	45.95
SD	1.888	1.915	2.286

b. Perhitungan *simplex lattice design*

- $A = 0$   
 $B = 1$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$32.28 = a(0) + b(1) + ab(0)(1)$$

$$b = 32.28$$

- $A = 1$

$$B = 0$$

$$Y = a(A) + b(B) + ab(A)(B)$$

$$45.95 = a(1) + b(0) + ab(1)(0)$$

$$a = 45.95$$

- $A = 0.5$

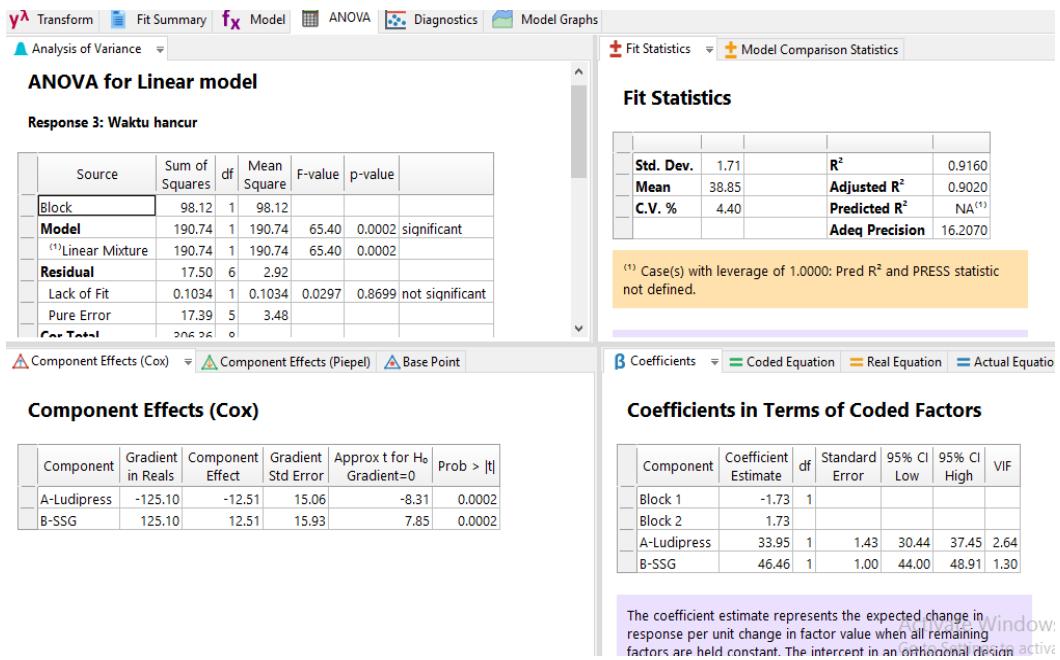
$$B = 0.5$$

$$Y = a(0.5) + b(0.5) + ab(A)(B)$$

$$38.32 = 32.28(0.5) + 45.92(0.5) + ab(0.5)(0.5)$$

$$ab = 3.18$$

### c. Hasil ANOVA



**Lampiran 9. Waktu pembasahan**

Replikasi	Waktu pembasahan (detik)		
	F1	F2	F3
R1	72.21	69.13	64.22
R2	72.96	68.94	65.53
R3	73.40	69.25	64.88
Rata-rata	72.85	69.106	64.87
SD	0.491	1.915	0.534

**Lampiran 10. Tanggap rasa dan waktu hancur *in vivo***

- a. Lembar kuisioner

**LEMBAR KUISIONER TANGGAP RASA *FAST DISINTEGRATING TABLET METOKLOPRAMID HCl***

Petunjuk pengisian :

1. Mengisi identitas diri pada tempat yang disediakan.
2. Cobalah satu formula *fast disintegrating tablet* yang sebelumnya berkumur terlebih dahulu dengan air putih, kemudian masukkan tablet ke dalam mulut dan biarkan tablet larut sendiri dan bercampur dengan saliva di dalam mulut, lalu coba formula berikutnya dengan cara yang sama.
3. Isilah penilaian anda pada kolom di bawah ini :

Identitas responden

Nama : .....

Usia : .....

Formula	Rasa tablet/detik		
	Manis	Agak pahit	Pahit
F1			
F2			
F3			

4. Berikan penilaian dengan memberi tanda centang (✓) pada form.

b. Data kuisioner

No	Nama responden	Tablet formula 1		Tablet formula 2		Tablet formula 3	
		Rasa	Wakt u hancu r (detik)	Rasa	Waktu hancur (detik)	Rasa	Waktu hancur (detik)
1	Diah Ayu	2	35.26	2	40.17	2	46.73
2	Rizky Perdana	3	34.76	3	39.77	3	45.87
3	Ary Krisna	2	33.48	2	38.83	2	47.69
4	Ismin Yulianti	2	32.11	2	39.34	2	45.32
5	Yurita	3	34.24	3	41.79	3	47.18
6	Rintya	2	32.87	2	39.63	2	47,34
7	Siti	2	34.69	2	38.37	2	45.61
8	Hanifah	2	33.49	2	40.65	2	47.70
9	Yuli Edi	3	34.12	3	40.88	3	46.33
10	Annisa	2	31.28	2	38.21	2	47.59
11	Eli	2	34.95	2	39.42	2	49.21
12	Sonia	3	33.65	3	41.76	3	46.68
13	Asis	2	35.26	2	40.75	2	47.22
14	Echy	3	33.82	3	39.88	3	48.85
15	Fatma	2	34.08	2	40.74	2	47.24
16	Januariska	2	34.47	2	39.73	2	48.54
17	Melisa	2	35.50	2	40.92	2	48.66
18	Indah	2	35.72	2	39.69	2	47.39
19	Adel	3	34.63	3	40.21	3	48.27
20	Githa	2	35.15	2	41.65	2	46.11
<b>Total dan rata-rata</b>		<b>0% manis 70% agak pahit 30% pahit</b>	<b>34.17 ± 1.13</b>	<b>0% manis 70% agak pahit 30% pahit</b>	<b>40.11 ± 1.03</b>	<b>0% manis 70% agak pahit 30% pahit</b>	<b>47.27 ± 1.09</b>

Keterangan :

1 : Manis

2 : Agak pahit

3 : Pahit

### Lampiran 11. $Q_3$ dan $DE_3$

a. Hasil disolusi

Formula 1				
Waktu (detik)				
	0.5	1	2	3
	40.6652	70.8022	81.8362	99.1177
	39.4054	72.0494	82.3401	97.6236
	38.3976	72.7952	83.8493	98.4021
Rata-rata	39.4894	71.8823	82.6752	98.3811
SD	1.1361313	1.006957007	1.04755043	0.747270636

Formula 2				
Waktu (detik)				
	0.5	1	2	3
	18.9972	24.7302	61.0048	93.9224
	18.4933	27.7486	61.7858	95.22
	19.5011	29.0184	62.5644	94.2323
Rata-rata	18.9972	27.1657	61.7850	94.4582
SD	0.5039	2.202717634	0.77980031	0.677662042

Formula 3				
Waktu (detik)				
	0.5	1	2	3
	11.9427	23.9038	51.6044	84.3474
	13.2023	24.9342	53.1388	83.2648
	12.9504	26.4334	51.6397	82.7609
Rata-rata	12.6985	25.0871	52.1276	83.4244
SD	0.6665	1.2726	0.8758	0.7559

b. Hasil  $\text{DE}_3$

<b><math>\text{DE}_3 (\%)</math></b>		
	F1	F2
	F3	
	91.03525	60.44988
	91.06296	61.97951
	91.93136	62.75328
<b>Rata-rata</b>	91.34319	61.72756
<b>SD</b>	0.509559	1.172187
		0.555323

c. Perhitungan *simplex lattice design Q<sub>3</sub>*

- A = 0  
B = 1

$$Y = a(A) + b(B) + ab(A)(B)$$

$$98.38 = a(0) + b(1) + ab(0)(1)$$

$$b = 98.38$$

- A = 1  
B = 0

$$Y = a(A) + b(B) + ab(A)(B)$$

$$83.42 = a(1) + b(0) + ab(1)(0)$$

$$a = 83.42$$

- A = 0.5  
B = 0.5

$$Y = a(0.5) + b(0.5) + ab(A)(B)$$

$$94.45 = 98.38(0.5) + 83.42(0.5) + ab(0.5)(0.5)$$

$$ab = 14.2$$

d. Perhitungan *simplex lattice design* DE<sub>3</sub>

- A = 0

B = 1

$$Y = a(A) + b(B) + ab(A)(B)$$

$$91.34 = a(0) + b(1) + ab(0)(1)$$

$$b = 91.34$$

- A = 1

B = 0

$$Y = a(A) + b(B) + ab(A)(B)$$

$$52.89 = a(1) + b(0) + ab(1)(0)$$

$$a = 52.89$$

- A = 0.5

B = 0.5

$$Y = a(0.5) + b(0.5) + ab(A)(B)$$

$$61.72 = 91.34(0.5) + 52.89(0.5) + ab(0.5)(0.5)$$

$$ab = 41.64$$

### ANOVA for Quadratic model

Response 4: Q3

Source	Sum of Squares	df	Mean Square	F-value	p-value
Block	97.87	1	97.87		
<b>Model</b>	263.63	2	131.82	261.75	< 0.0001 significant
( <sup>(1)</sup> )Linear Mixture	242.42	1	242.42	481.37	< 0.0001
AB	21.21	1	21.21	42.12	0.0013
Pure Error	2.52	5	0.5036		
Cor Total	364.02	8			

(<sup>(1)</sup>) Inference for linear mixtures uses Type I sums of squares.

Mixture Component coding is L\_Pseudo.  
Sum of squares is Type III - Partial

The Model F-value of 261.75 implies the model is significant. There is only a 0.01% chance that an F-value this large could occur due to noise.

P-values 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.

### Fit Statistics

Std. Dev.	0.7097	R <sup>2</sup>	0.9905
Mean	92.09	Adjusted R <sup>2</sup>	0.9868
C.V. %	0.7706	Predicted R <sup>2</sup>	NA <sup>(1)</sup>

(<sup>(1)</sup>) Case(s) with leverage of 1.0000: Pred R<sup>2</sup> and PRESS statistic not defined.

B Coefficients C Coded Equation R Real Equation D Actual Equation

### Coefficients in Terms of Coded Factors

Component	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Block 1	0.4976	1				
Block 2	-0.4976					
A-Ludipress	97.88	1	0.5973	96.35	99.42	2.66
B-SSG	83.26	1	0.4346	82.14	84.38	1.41
AB	13.56	1	2.09	8.19	18.93	1.62

Activate Windows

The coefficient estimate represents the expected change in

### Hasil ANOVA Q<sub>3</sub>

### e. Hasil ANOVA DE<sub>3</sub>

#### ANOVA for Quadratic model

Response 5: DE3

Source	Sum of Squares	df	Mean Square	F-value	p-value
Block	278.02	1	278.02		
<b>Model</b>	2168.03	2	1084.02	1304.53	< 0.0001 significant
( <sup>(1)</sup> )Linear Mixture	1972.45	1	1972.45	2373.70	< 0.0001
AB	195.58	1	195.58	235.36	< 0.0001
Pure Error	4.15	5	0.8310		
Cor Total	2450.20	8			

(<sup>(1)</sup>) Inference for linear mixtures uses Type I sums of squares.

Mixture Component coding is L\_Pseudo.  
Sum of squares is Type III - Partial

The Model F-value of 1304.53 implies the model is significant. There is only a 0.01% chance that an F-value this large could occur due to noise.

P-values 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.

### Fit Statistics

Std. Dev.	0.9116	R <sup>2</sup>	0.9981
Mean	68.61	Adjusted R <sup>2</sup>	0.9973
C.V. %	1.33	Predicted R <sup>2</sup>	NA <sup>(1)</sup>

(<sup>(1)</sup>) Case(s) with leverage of 1.0000: Pred R<sup>2</sup> and PRESS statistic not defined.

B Coefficients C Coded Equation R Real Equation D Actual Equation

### Coefficients in Terms of Coded Factors

Component	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Block 1	-0.0967	1				
Block 2	0.0967					
A-Ludipress	91.44	1	0.7672	89.47	93.41	2.66
B-SSG	52.79	1	0.5582	51.36	54.23	1.41
AB	-41.17	1	2.68	-48.07	-34.27	1.62

Activate Windows

The coefficient estimate represents the expected change in

## Lampiran 12. Kurva baku

### a. Pembuatan larutan baku metoklopramid HCl

Larutan baku 113 ppm dibuat dengan menimbang sebanyak 11,3 mg dan dimasukkan dalam labu tentukur 100 mL dan tambahkan *aquadestillata* sampai tanda batas.

- Perhitungan bahan :

Kertas kosong : 0,5695 gram

Zat aktif : 0,01 gram

Kertas + zat aktif : 0,5814 gram

Sisa pada kertas : 0,5701

$$\text{Zat aktif} = (\text{kertas} + \text{zat aktif}) - (\text{sisa pada kertas})$$

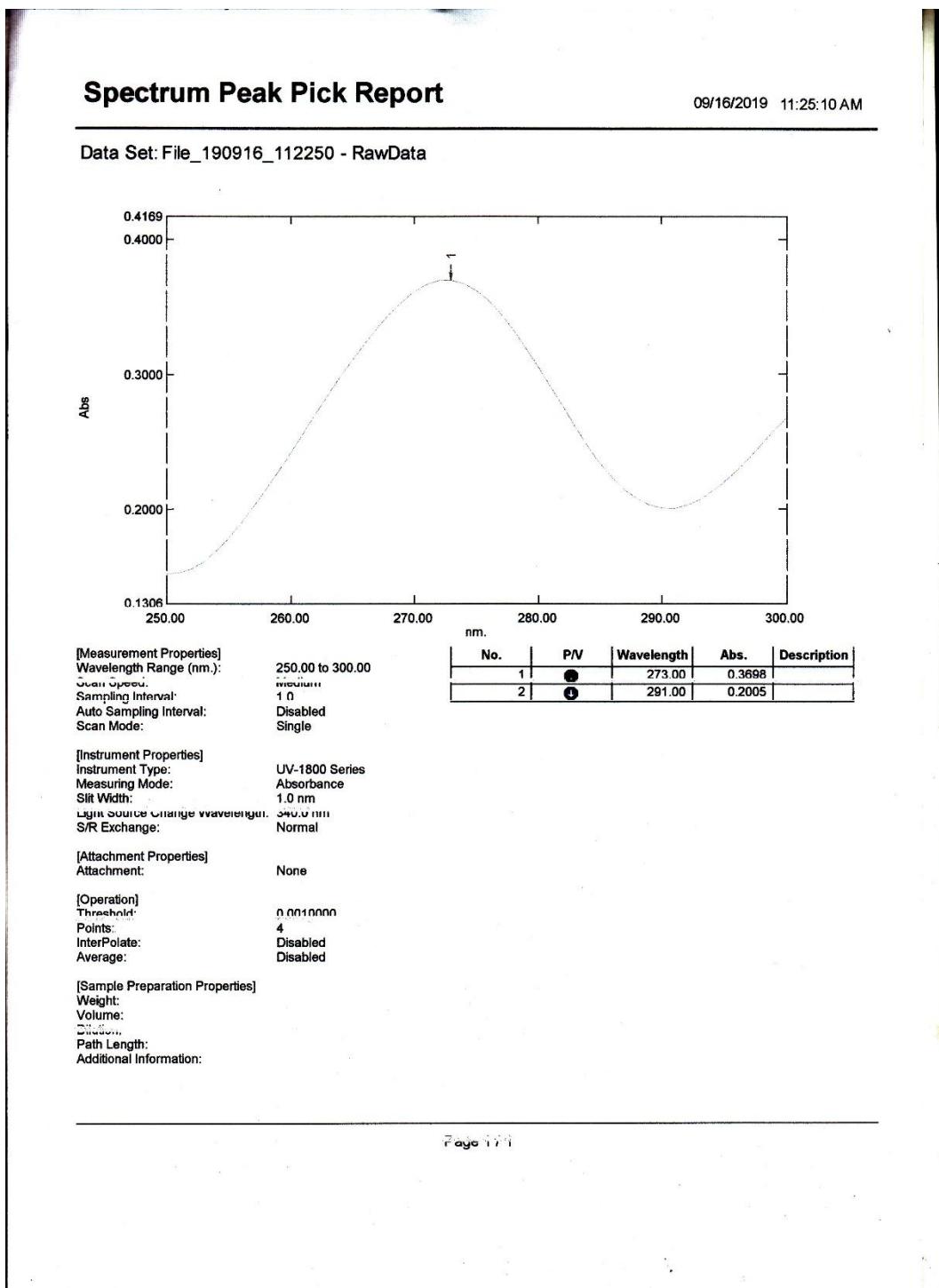
$$= 0,5814 - 0,5701$$

$$= 0,0113 \text{ gram}$$

$$= 11,3 \text{ mg}/100 \text{ mL}$$

$$= 113 \text{ ppm}$$

b. Panjang gelombang maksimum



*c. Operating time***Kinetics Data Print Report**

09/16/2019 12:28:21 PM

Time ( Minute )	RawData ...	RawData ...
0.000	2.060	0.376
1.000	2.056	0.376
2.000	2.052	0.377
3.000	2.059	0.375
4.000	2.053	0.376
5.000	2.047	0.376
6.000	2.049	0.375
7.000	2.050	0.375
8.000	2.054	0.375
9.000	2.050	0.375
10.000	2.054	0.376
11.000	2.056	0.375
12.000	2.052	0.376
13.000	2.046	0.376
14.000	2.049	0.375
15.000	2.051	0.375
16.000	2.049	0.375
17.000	2.055	0.374
18.000	2.054	0.375
19.000	2.053	0.374
20.000	2.056	0.374
21.000	2.049	0.375
22.000	2.049	0.374
23.000	2.048	0.374
24.000	2.047	0.375
25.000	2.043	0.375
26.000	2.047	0.374
27.000	2.048	0.375
28.000	2.049	0.375
29.000	2.051	0.375
30.000	2.054	0.375

d. Kurva kalibrasi

Ambil 1 mL dari larutan baku metoklopramid HCl yang telah dibuat, dimasukkan ke dalam labu tentukur 25 mL dan tambahkan *aquadestillata* sampai tanda batas, ukur serapannya pada panjang gelombang maksimumnya 273 nm.

- Pengenceran

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$1 \cdot 113 = 25 \cdot C_2$$

$$C_2 = 4,52 \text{ ppm}$$

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$2 \cdot 113 = 25 \cdot C_2$$

$$C_2 = 9,04 \text{ ppm}$$

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$3 \cdot 113 = 25 \cdot C_2$$

$$C_2 = 13,56 \text{ ppm}$$

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$4 \cdot 113 = 25 \cdot C_2$$

$$C_2 = 18,08 \text{ ppm}$$

$$V_1 \cdot C_1 = V_2 \cdot C_2$$

$$5 \cdot 113 = 25 \cdot C_2$$

$$C_2 = 22,6 \text{ ppm}$$

e. Persamaan regresi linier

X (ppm)	Y (abs)
4.52	0.221
9.04	0.372
13.56	0.563
18.08	0.738
22.6	0.935

Nilai a = 0.0276

b = 0.03969

r = 0.9991

f. Hasil uji disolusi

### FORMULA 1

Tablet 1

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.189	1	4.0665	3.6599	0.0000	0.0000	4.0665	40.6652	20.33258	
1	0.307	1	7.0396	6.3356	0.0407	0.0407	7.0802	70.8022	55.73369	409.6586
2	0.348	1	8.0726	7.2653	0.0704	0.1111	8.1836	81.8362	152.6384	91.343
3	0.415	1	9.7606	8.7846	0.0807	0.1511	9.9118	99.1177	180.9539	

Keterangan :

- Fp = faktor pengenceran
- Kadar obat (ppm) = kadar zat aktif dalam 1 liter
- Kadar obat dalam 900 mL (mg) = kadar zat aktif dalam media disolusi
- Koreksi = koreksi pada saat sampling
- Q = jumlah zat aktif yang terdisolusi
- % disolusi = % zat aktif yang terdisolusi ke dalam media disolusi

AUC = luas area dibawah kurva

DE (%) = disolusi efisiensi

Contoh perhitungan Formula 1 replikasi 1 (menit ke-3 atau Q<sub>3</sub>) :

- Kadar obat (ppm) :  $y = a + bx$

$$0.415 = 0.027 + 0.03969x$$

$$x = 9.7606$$

$$9.7606 \times 1 \text{ (faktor pengenceran)} = 9.7606$$

- Kadar obat dalam 900 mL (mg) : Kadar = kadar obat (ppm) x 0,9

$$= 9.7606 \times 0.9$$

$$= 8.7846$$

- Koreksi : Koreksi =  $\frac{volume\ sampling}{volume\ medium\ disolusi} \times$  kadar obat dalam 900 mL pada pengambilan sampling sebelumnya (mg)

$$= \frac{10}{900} \times 7.2653$$

$$= 0.0807$$

- Total koreksi : Total koreksi = koreksi pada pengambilan sampling sebelumnya + koreksi  

$$= 0.0704 + 0.0807$$

$$= 0.1511$$
- $Q_3$  (jumlah zat aktif yang terdisolusi) :  $Q = \text{total koreksi menit ke-3} + \text{kadar obat (ppm) menit ke-3}$   

$$= 0.1511 + 9.7606$$

$$= 9.9118$$
- % disolusi :  $\% \text{ disolusi}_3 = \frac{\text{jumlah zat aktif terdisolusi menit ke-3}}{\text{kadar zat aktif}} \times 100 \%$   

$$= \frac{9.9118}{10} \times 100\%$$

$$= 99.1177 \%$$
- AUC :  $AUC = (\text{Waktu ke-n} - \text{menit pada waktu sebelumnya}) \times (\% \text{ disolusi} + \% \text{ disolusi sebelumnya})$   

$$= (3 - 2) \times (99.1177 + 81.8362)$$

$$= 180.9539$$

DE :  $DE = \frac{AUC \text{ Total}}{\text{bobot tablet} \times \text{waktu sampling}} = \frac{409.6586}{150 \times 3}$

$$= 91.343$$

Tablet 2

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.184	1	3.9405	3.5465	0.0000	0.0000	3.9405	39.4054	19.7027	
1	0.312	1	7.1655	6.4490	0.0394	0.0394	7.2049	72.0494	55.7273	409.7833 91.062
2	0.35	1	8.1230	7.3107	0.0717	0.1111	8.2340	82.3401	154.3895	
3	0.409	1	9.6095	8.6485	0.0812	0.1529	9.7624	97.6236	179.9637	

Tablet 3

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.18	1	3.8398	3.4558	0.0000	0.0000	3.8398	38.3976	19.1987	
1	0.315	1	7.2411	6.5170	0.0384	0.0384	7.2795	72.7952	55.5963	413.6911 91.931
2	0.356	1	8.2741	7.4467	0.0724	0.1108	8.3849	83.8493	156.6445	
3	0.412	1	9.6851	8.7166	0.0827	0.1552	9.8402	98.4021	182.2514	

Tablet 4

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.182	1	3.8901	3.5011	0.0000	0.0000	3.8901	38.9015	19.45074	
1	0.310	1	7.0899	6.4036	0.0389	0.0389	7.1540	71.5404	55.22096	406.974
2	0.348	1	8.1230	7.2653	0.0712	0.1101	8.1826	81.8262	153.3666	90.438
3	0.407	1	9.8110	8.6032	0.0807	0.1519	9.7110	97.1096	178.9358	

Tablet 5

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.191	1	4.1169	3.7052	0.0000	0.0000	4.1169	41.1691	20.58453	
1	0.309	1	7.0899	6.3810	0.0412	0.0412	7.1311	71.3112	56.24011	412.4679
2	0.350	1	8.1230	7.3107	0.0709	0.1121	8.2350	82.3502	153.6614	91.659
3	0.417	1	9.8110	8.8299	0.0812	0.1521	9.9632	99.6316	181.9819	

Tablet 6

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml (mg)	Koreksi	Total koreksi	Q	% Disolusi	AUC	DE
										Total
										AUC
0	0	0	0	0	0	0	0	0	0	
0.5	0.18	1	3.8398	3.4558	0.0000	0.0000	3.8398	38.3976	19.1987	
1	0.315	1	7.2411	6.5170	0.0384	0.0384	7.2795	72.7952	55.5963	413.6911 91.931
2	0.356	1	8.2741	7.4467	0.0724	0.1108	8.3849	83.8493	156.6445	
3	0.412	1	9.6851	8.7166	0.0827	0.1552	9.8402	98.4021	182.2514	

## FORMULA 2

Tablet 1

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat	Koreksi	Total	Q	% Disolusi	AUC	DE
				dalam 900 ml						
0	0	0	0	0	0	0	0	0		
0.5	0.103	1	1.8997	1.7098	0.0000	0.0000	1.8997	18.9972	9.4986	
1	0.205	1	2.4540	4.0227	0.0190	0.0190	4.4886	44.8864	31.9418	302.8634 67.303
2	0.268	1	6.0569	5.4512	0.0447	0.0637	6.1206	61.2063	106.0927	
3	0.397	1	9.3071	8.3764	0.0606	0.1053	9.4124	94.1240	155.3303	

Tablet 2

<b>Menit</b>	<b>Absorbansi</b>	<b>Fp</b>	<b>Kadar</b>	<b>Kadar obat</b>	<b>Koreksi</b>	<b>Total</b>	<b>Q</b>	<b>%</b>	<b>AUC</b>	<b>DE</b>
			<b>obat</b>	<b>dalam 900 ml</b>						
<b>(ppm)</b>										
<b>0</b>	0	0	0	0	0	0	0	0		
<b>0.5</b>	0.101	1	1.8493	1.6644	0.0000	0.0000	1.8493	18.4933	9.2466	
<b>1</b>	0.208	1	4.5452	4.0907	0.0185	0.0185	4.5637	45.6372	32.0652	306.2774 68.061
<b>2</b>	0.271	1	6.1325	5.5193	0.0455	0.0639	6.1965	61.9647	107.6019	
<b>3</b>	0.402	1	9.4331	8.4898	0.0613	0.1068	9.5399	95.3988	157.3636	

Tablet 3

<b>Menit</b>	<b>Absorbansi</b>	<b>Fp</b>	<b>Kadar</b>	<b>Kadar obat</b>	<b>Koreksi</b>	<b>Total</b>	<b>Q</b>	<b>%</b>	<b>AUC</b>	<b>DE</b>
			<b>obat</b>	<b>dalam 900 ml</b>						
<b>(ppm)</b>										
<b>0</b>	0	0	0	0	0	0	0	0		
<b>0.5</b>	0.105	1	1.9501	1.7551	0.0000	0.0000	1.9501	19.5011	9.7505	
<b>1</b>	0.204	1	4.4444	4.0000	0.0195	0.0195	4.4639	44.6395	32.07029	282.3898 68.064
<b>2</b>	0.274	1	6.2081	5.5873	0.0444	0.0639	6.2721	62.7206	107.36	
<b>3</b>	0.392	1	9.3323	8.3991	0.0621	0.1065	9.4389	94.3885	157.1091	

Tablet 4

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total	Q	% Disolusi	AUC	DE
									koreksi	Total AUC
0	0	0	0	0	0	0	0	0		
0.5	0.105	1	1.9501	1.7551	0.0000	0.0000	1.9501	19.5011	9.75056	
1	0.207	1	4.5200	4.0680	0.0190	0.0195	4.5395	45.3953	32.44822	305.6727 67.927
2	0.270	1	6.1073	5.4966	0.0447	0.0647	6.1720	61.7203	107.1156	
3	0.399	1	9.3575	8.4218	0.0606	0.1063	9.4638	94.6379	156.3583	

Tablet 5

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total	Q	% Disolusi	AUC	DE
									koreksi	Total AUC
0	0	0	0	0	0	0	0	0		
0.5	0.101	1	1.8493	1.6644	0.0000	0.0000	1.8493	18.4933	9.2466	
1	0.208	1	4.5452	4.0907	0.0185	0.0185	4.5637	45.6372	32.0652	306.2774 68.061
2	0.271	1	6.1325	5.5193	0.0455	0.0639	6.1965	61.9647	107.6019	
3	0.402	1	9.4331	8.4898	0.0613	0.1068	9.5399	95.3988	157.3636	

Tablet 6

<b>Menit</b>	<b>Absorbansi</b>	<b>Fp</b>	<b>Kadar</b>	<b>Kadar obat</b>	<b>Koreksi</b>	<b>Total</b>	<b>Q</b>	<b>%</b>	<b>AUC</b>	<b>DE</b>
			<b>obat</b> <b>(ppm)</b>	<b>dalam 900 ml</b>		<b>koreksi</b>		<b>Disolusi</b>		<b>Total AUC</b>
<b>0</b>	0	0	0	0	0	0	0	0		
<b>0.5</b>	0.103	1	1.8997	1.7098	0.0000	0.0000	1.8997	18.9972	9.4986	
<b>1</b>	0.202	1	4.3941	3.9546	0.0190	0.0190	4.4131	44.1305	31.5638	303.4807 67.4401
<b>2</b>	0.272	1	6.1577	5.5420	0.0439	0.0629	6.2207	62.2066	106.3371	
<b>3</b>	0.396	1	9.2819	8.3537	0.0616	0.1055	9.3875	93.8745	156.0811	

## FORMULA 3

Tablet 1

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total koreksi	Q	%	AUC	DE	Total AUC
0	0	0	0	0	0	0	0	0			
0.5	0.075	1	1.1943	1.0748	0.0000	0.0000	1.1943	12.1739	6.086929		
1	0.122	1	2.3784	2.1406	0.0119	0.0119	2.3904	24.3667	18.27029	238.0131	52.278
2	0.231	1	5.1247	4.6122	0.0238	0.0357	5.1604	52.6039	76.97063		
3	0.352	1	8.1733	7.3560	0.0512	0.0750	8.2484	84.0813	136.6852		

Tablet 2

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total koreksi	Q	%	AUC	DE	Total AUC
											Disolusi
0	0	0	0	0	0	0	0	0	0	0	
0.5	0.08	1	1.3202	1.1882	0.0000	0.0000	1.3202	13.2023	6.6011		
1	0.126	1	2.4792	2.2313	0.0132	0.0132	2.4924	24.9242	19.0632	240.131	53.362
2	0.237	1	5.2759	4.7483	0.0248	0.0380	5.3139	53.1388	78.0629		
3	0.359	1	8.3497	7.5147	0.0528	0.0776	8.3265	83.2648	136.4036		

Tablet 3

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total koreksi	Q	%	AUC	DE	Total AUC
											Disolusi
0	0	0	0	0	0	0	0	0	0	0	
0.5	0.079	1	1.2950	1.1655	0.0000	0.0000	1.2950	13.2012	6.4751		
1	0.132	1	2.6304	2.3673	0.0130	0.0130	2.6433	26.9453	19.6918	238.6407	53.301
2	0.231	1	5.1247	4.6122	0.0263	0.0393	5.1640	52.6399	78.0730		
3	0.353	1	8.1985	7.3787	0.0512	0.0776	8.2761	82.7609	134.4006		

Tablet 4

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total koreksi	Q	%	AUC	DE	Total AUC
											Disolusi
0	0	0	0	0	0	0	0	0			
0.5	0.073	1	1.1439	1.0295	0.0000	0.0000	1.1439	11.4386	5.7193		
1	0.120	1	2.3280	2.0952	0.0114	0.0114	2.3395	23.3948	17.4167	232.4452	51.654
2	0.229	1	5.0743	4.5669	0.0233	0.0347	5.1090	51.0905	74.4852		
3	0.357	1	8.2993	7.4694	0.0507	0.0740	8.3733	83.7334	134.8239		

Tablet 5

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat dalam 900 ml	Koreksi	Total koreksi	Q	%	AUC	DE	Total AUC
											Disolusi
0	0	0	0	0	0	0	0	0			
0.5	0.082	1	1.3706	1.2336	0.0000	0.0000	1.3706	13.7062	6.8531		
1	0.128	1	2.5296	2.2766	0.0137	0.0137	2.5433	25.4331	19.5696	242.940	53.986
2	0.239	1	5.3263	4.7937	0.0253	0.0390	5.3653	53.6528	79.0859		
3	0.357	1	8.2993	7.4694	0.0533	0.0786	8.3779	83.7788	137.431		

Tablet 6

Menit	Absorbansi	Fp	Kadar obat (ppm)	Kadar obat	Koreksi	Total	Q	%	AUC	DE
				dalam 900 ml		koreksi			Disolusi	
<b>0</b>	0	0	0	0	0	0	0	0		
<b>0.5</b>	0.079	1	1.2950	1.1655	0.0000	0.0000	1.2950	13.2012	6.4751	
<b>1</b>	0.132	1	2.6304	2.3673	0.0130	0.0130	2.6433	26.9453	19.6918	238.6407 53.301
<b>2</b>	0.231	1	5.1247	4.6122	0.0263	0.0393	5.1640	52.6399	78.0730	
<b>3</b>	0.353	1	8.1985	7.3787	0.0512	0.0776	8.2761	82.7609	134.4006	

**Lampiran 13. Nilai penerimaan keseragaman kandungan**

Tablet	Berat	Volume	Fp	Absorbansi	Formula 1		Percentase (%)	
					Konsentrasi	mg		
	(mg)	(mL)		(ppm)	ppm	mg	tablet mg	
1	154	100	10	0.412	9.6851	9.9433	10.2085	102.0848
2	154	100	10	0.411	9.6599	9.9175	10.1819	101.8193
3	154	100	10	0.409	9.6095	9.8657	10.1288	101.2881
4	154	100	10	0.411	9.6599	9.9175	10.1819	101.8193
5	152	100	10	0.405	9.5087	9.6355	9.7639	97.6395
6	152	100	10	0.401	9.4079	9.5334	9.6605	96.6046
7	152	100	10	0.406	9.5339	9.6610	9.7898	97.8982
8	153	100	10	0.41	9.6347	9.8274	10.0239	100.2391
9	153	100	10	0.408	9.5843	9.7760	9.9715	99.7148
10	153	100	10	0.409	9.6095	9.8017	9.9977	99.9770
						Rata-rata	9.9908	99.9085
						SD		1.9493
						NP		4.6783

Contoh perhitungan :

### FORMULA 1

$$NP = [ M - X_{\text{rata-rata}} ] + ks$$

Keterangan :

NP = Nilai penerimaan

$X_{\text{rata-rata}}$  = Rata-rata kandungan dari masing-masing kandungan

k = Konstanta penerimaan, jika n=10 maka k=2,4 dan n=30 maka k=2,0

s = Simpangan baku sampel

M = Jika  $98,5\% \leq X_{\text{rata-rata}} \leq 101,5\%$  maka  $M = X_{\text{rata-rata}}$

Jika  $X_{\text{rata-rata}} < 98,5\%$  maka  $M = 98,5\%$

Jika  $X_{\text{rata-rata}} > 101,5\%$  maka  $M = 101,5\%$

$T(\text{rata-rata}) = \leq 101\%,$  maka  $M = 98,5 \leq X_{\text{rata-rata}} \leq 101,5\%$

$$NP = [ M - X_{\text{rata-rata}} ] + ks$$

$$= [99.9085 - 99.9085] + 2,4 \times 1,9493$$

$$= 4,678\%$$

Tablet	Berat	Volume	Fp	Absorbansi	Formula 2		Percentase (%)	
					Konsentrasi			
					(mg)	(mL)	(ppm)	ppm
1	151	100	10	0.415	9.7606	9.8257	9.8912	98.9122
2	151	100	10	0.406	9.5339	9.5974	9.6614	96.6143
3	151	100	10	0.41	9.6347	9.6989	9.7636	97.6356
4	151	100	10	0.412	9.6851	9.7496	9.8146	98.1462
5	152	100	10	0.412	9.6851	9.8142	9.9450	99.4505
6	152	100	10	0.419	9.8614	9.9929	10.1262	101.2615
7	152	100	10	0.427	10.0630	10.1972	10.3331	103.3312
8	153	100	10	0.411	9.6599	9.8531	10.0501	100.5012
9	153	100	10	0.414	9.7354	9.9302	10.1288	101.2876
10	153	100	10	0.409	9.6095	9.8017	9.9977	99.9770
						Rata-rata	9.9712	99.7117
						SD		1.9928
						NP		4.7827

Tablet	Berat	Volume	Fp	Absorbansi	Formula 3		Percentase (%)	
					Konsentrasi			
					(mg)	(mL)	(ppm)	ppm
1	151	100	10	0.421	9.9118	9.9118	9.9779	99.7790
2	151	100	10	0.419	9.8614	9.8614	9.9272	99.2717
3	151	100	10	0.415	9.7606	9.7606	9.8257	98.2572
4	151	100	10	0.413	9.7103	9.7103	9.7750	97.7499
5	153	100	10	0.417	9.8110	9.8110	10.0073	100.0726
6	153	100	10	0.42	9.8866	9.8866	10.0844	100.8435
7	153	100	10	0.422	9.9370	9.9370	10.1358	101.3575
8	155	100	10	0.408	9.5843	9.5843	9.9038	99.0375
9	155	100	10	0.405	9.5087	9.5087	9.8256	98.2565
10	155	100	10	0.407	9.5591	9.5591	9.8777	98.7772
					Rata-rata	9.9340	99.3403	
					SD		1.1713	
					NP		2.8112	

**Lampiran 14. Validasi metode analisis**

a. Penentuan LOD dan LOQ

X (ppm)	Y (abs)	Y'	Y-Y'	(Y-Y')^2
<b>4.52</b>	0.221	0.207	0.0140	0.000196000000000000
<b>9.04</b>	0.372	0.3864	-0.0144	0.000207360000000000
<b>13.56</b>	0.563	0.5658	-0.0028	0.000007840000000000
<b>18.08</b>	0.738	0.7452	-0.0072	0.000051840000000000
<b>22.6</b>	0.935	0.9246	0.0104	0.000108160000000000
				<b>Total</b> 0.00057
<b>a = 0.0276</b>				S <sub>y/x</sub> 0.01380
<b>b = 0.03969</b>				LOD 1.147264
<b>r = 0.999114</b>				LOQ 3.476558

Nilai  $y'$  diperoleh dari substitusi konsentrasi dalam persamaan  $y' = 0.0276 + 0.03969x$  dengan  $x$  adalah konsentrasi (ppm) dan  $y$  absorbansi ( $y'$ )

$$S_{x/y} = \sqrt{\frac{\sum (y - y')^2}{(N-2)}}$$

$S_{x/y}$  = simpangan baku residual

$N$  = jumlah data

$\sum (y - y')^2$  = jumlah kuadrat total residual

$$\begin{aligned} S_{x/y} &= \sqrt{\frac{\sum (y - y')^2}{(N-2)}} \\ &= \sqrt{\frac{0.00057}{(5-2)}} = 0.01380 \end{aligned}$$

- $LOD = 3,3 \times \frac{S_{x/y}}{b}$

$$= 3,3 \times \frac{0.01380}{0.03969}$$

$$= 1.147264$$

- $LOQ = 10 \times \frac{S_{x/y}}{b}$

$$= 10 \times \frac{0.01380}{0.03969}$$

$$= 3.476558$$

b. Penentuan perolehan kembali (*recovery*) akurasi

Konsentrasi	Replikasi	Absorbansi	Konsentrasi	Sebenarnya	%	% Recovery
80% (9.04 ppm)	1	0.379	8.8536	9.04	98%	98.03%
	2	0.38	8.8788	9.04	98%	
	3	0.379	8.8536	9.04	98%	
100% (13.56 ppm)	1	0.568	13.6154	13.56	100%	99.91%
	2	0.561	13.4391	13.56	99%	
	3	0.567	13.5902	13.56	100%	99.00%
120% (18.08 ppm)	1	0.732	17.7474	18.08	98%	99.04%
	2	0.744	18.0498	18.08	100%	
	3	0.739	17.9238	18.08	99%	

c. Penentuan RSD (standar deviasi relatif)

Konsentrasi (ppm)	Replikasi	Absorbansi	Konsentrasi (ppm)
13.56	1	0.574	13.7666
	2	0.577	13.8422
	3	0.579	13.8926
	4	0.573	13.7414
	5	0.566	13.5650
	6	0.567	13.5902
		SD	0.132044
		Rata-rata	13.73301
		RSD	0.009615

$$RSD = \frac{100\% \times SD}{\bar{x}}$$

$$= \frac{100\% \times 0.132044}{13.73301}$$

$$= 0.009615$$

Keterangan :

RSD = standar deviasi relatif (%)

SD = Standar deviasi

$\bar{X}$

=

rata-rata

(mean)

### Lampiran 15. One sample t-test

#### a. Prediksi formula optimum

**Factors**

	Component	Name	Level	Low Level	High Level	Std. Dev.	Coding
	A	Ludipress	87.00	78.00	87.00	0.0000	Actual
	B	SSG	3.00	3.00	12.00	0.0000	Actual
		Total =	90.00				

**Point Prediction**

Two-sided Confidence = 95% Population = 99%

	Solution 1 of 1 Response	Predicted Mean	Predicted Median	Observed	Std Dev	SE Mean	95% CI low for Mean	95% CI high for Mean	95% TI low for 99% Pop	95% TI high for 99% Pop
	Kekerasan	3.86845	3.86845		0.0141627	0.0118927	3.83935	3.89755	3.77546	3.96143
	Kerapuhan	0.924231	0.924231		0.005547	0.00465792	0.912833	0.935628	0.887812	0.96065
	Waktu hancur	33.9451	33.9451		1.70774	1.43402	30.4362	37.4541	22.7329	45.1574
	Q3	97.8835	97.8835		0.709652	0.597261	96.3482	99.4188	92.861	102.906
	DE3	91.4394	91.4394		0.911572	0.767202	89.4673	93.4116	84.9878	97.8911

b. Kekerasan tablet

**One-Sample Kolmogorov-Smirnov Test**

		Kekerasan
N		3
Normal Parameters <sup>a,b</sup>	Mean	3.85267
	Std. Deviation	.024502
	Absolute	.176
Most Extreme Differences	Positive	.176
	Negative	-.173
Kolmogorov-Smirnov Z		.305
Asymp. Sig. (2-tailed)		1.000

**One-Sample Statistics**

	N	Mean	Std. Deviation	Std. Error Mean
Kekerasan	3	3.85267	.024502	.014146

a. Test distribution is Normal.

b. Calculated from data.

**One-Sample Test**

	Test Value = 3.868					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Kekerasan	-1.084	2	.392	-.015333	-.07620	.04553

c. Kerapuhan

**One-Sample Kolmogorov-Smirnov Test**

		Kerapuhan
N		3
Normal Parameters <sup>a,b</sup>	Mean	.93565
	Std. Deviation	.038592
	Absolute	.240
Most Extreme Differences	Positive	.240
	Negative	-.193
Kolmogorov-Smirnov Z		.416
Asymp. Sig. (2-tailed)		.995

**One-Sample Statistics**

	N	Mean	Std. Deviation	Std. Error Mean
Kerapuhan	3	.93565	.038592	.022281

a. Test distribution is Normal.

b. Calculated from data.

**One-Sample Test**

	Test Value = 0.920					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Kerapuhan	.702	2	.555	.015648	-.08022	.11152

d. Waktu hancur

**One-Sample Kolmogorov-Smirnov Test**

		Waktu hancur
N		3
Normal Parameters <sup>a,b</sup>	Mean	33.17000
	Std. Deviation	1.467072
Most Extreme Differences	Absolute	.191
	Positive	.191
	Negative	-.182
Kolmogorov-Smirnov Z		.331
Asymp. Sig. (2-tailed)		1.000

**One-Sample Statistics**

	N	Mean	Std. Deviation	Std. Error Mean
Waktu hancur	3	33.17000	1.467072	.847014

a. Test distribution is Normal.

b. Calculated from data.

**One-Sample Test**

	Test Value = 33.945					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
Waktu hancur	-.915	2	.457	-.775000	-4.41941	2.86941

e. Q<sub>3</sub>

**One-Sample Kolmogorov-Smirnov Test**

		Q3
N		3
Normal Parameters <sup>a,b</sup>	Mean	97.95273
	Std. Deviation	.861673
	Absolute	.210
Most Extreme Differences	Positive	.210
	Negative	-.187
Kolmogorov-Smirnov Z		.365
Asymp. Sig. (2-tailed)		.999

a. Test distribution is Normal.

b. Calculated from data.

**One-Sample Statistics**

	N	Mean	Std. Deviation	Std. Error Mean
Q3	3	97.95273	.861673	.497487

**One-Sample Test**

	Test Value = 97.883					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
Q3	.140	2	.901	.069733	-2.07078	2.21025

f. DE<sub>3</sub>

**One-Sample Kolmogorov-Smirnov Test**

		DE3
N		3
Normal Parameters <sup>a,b</sup>	Mean	91.19387
	Std. Deviation	.448351
	Absolute	.184
Most Extreme Differences	Positive	.184
	Negative	-.180
Kolmogorov-Smirnov Z		.318
Asymp. Sig. (2-tailed)		1.000

**One-Sample Statistics**

	N	Mean	Std. Deviation	Std. Error Mean
DE3	3	91.19387	.448351	.258856

a. Test distribution is Normal.

b. Calculated from data.

**One-Sample Test**

	Test Value = 91.439					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
DE3	-.947	2	.444	-.245133	-1.35890	.86863

## Lampiran 16. Alat-alat penelitian



Cube mixer



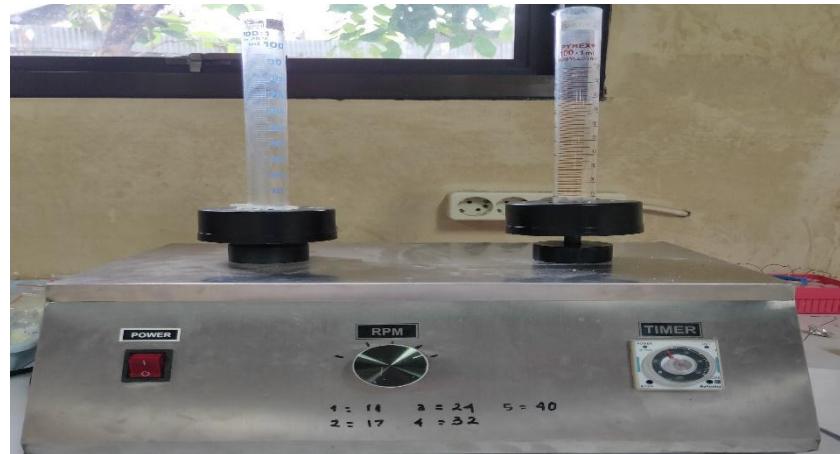
Mesin cetak tablet



Friabilator



*Disintegration tester*



*Tapped density*



*Waktu alir*



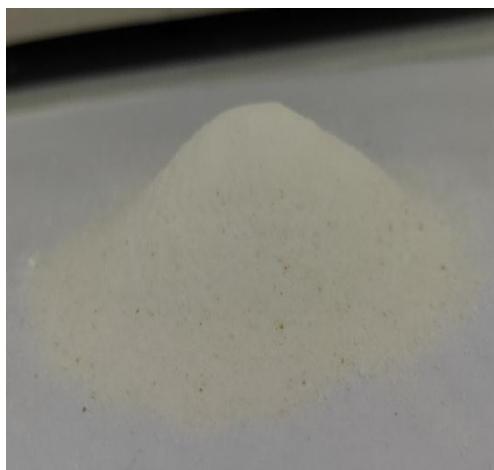
*Dissolution tester*



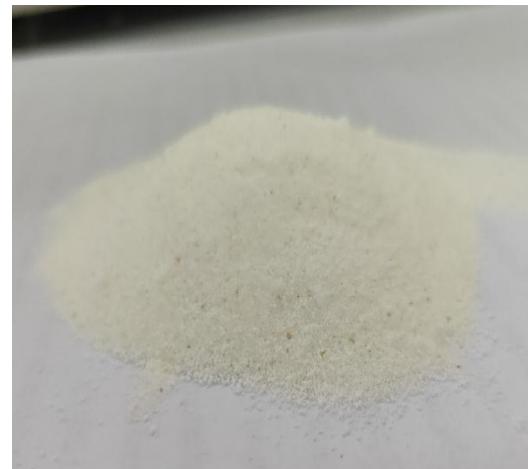
*Hardness tester*

Spektrofotometer Uv-Vis

**Lampiran 17. Hasil tablet FDT metoklopramid HCl**

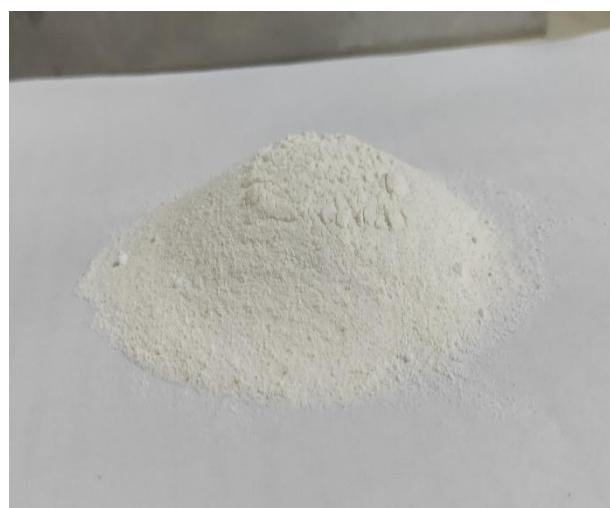
**Lampiran 18. Pengujian waktu alir serbuk**

Formula 1



Formula 2

Formula 3



**Lampiran 19. Pengujian waktu pembasahan**

Formula 1



Formula 2



Formula 3



Perbandingan ke-3 formula

