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LAMPIRAN 1

SERTIFIKAT ANALISIS BAHAN BAKU

Kimia Farma (Persero)
Bandung
Pahlawan No 29 - 31 Bandung 40171
Telp. 022- 4204043 Fax. 022-4237079

kimia farma

INSPECTION REPORT

Bahan aktif

Inspection Lot	: 10000029075	Start Inspection Date	: 13.02.2018
Material Document	: 5000818316/0001/2018	End Inspection Date	: 14.02.2018
Material Number	: 31000239	Inspected By	: SEPTIAN
Material Description	: RANITIDINE HYDROCHLORIDE	Production Date	: 01.10.2017
Batch Number	: 0000031477	Expiration Date	: 30.09.2021
Vendor Batch	: RH1020171316	Next Inspection Date	: 19.02.2019
Lot Size	: 125 KG 6 DRM	Purchase Order	: 5000006838
Sample Size	: 0.031 KG 4 DRM	Manufacturer	: SAPACA LABORATORIES LIMITED
Vendor	: MENJANGAN SAKTI, PT	Sampling Date	: 09.02.2018
		Sampling By	: Zola

Characteristic	Result	Unit	Specification	Method
Bentuk	Serbuk atau serbuk kristal		Serbuk atau serbuk kristal	USP 36
Warna	Putih sampai kuning pucat		Putih sampai kuning pucat	USP 36
Bau	Tidak berbau		Tidak berbau	USP 36
Susut Pengeringan (%)	0.66	%	0.00 - 0.75	USP 36
Sisa Pemijaran (%)	0.01	%	0.00 - 0.10	USP 36
Kadar (%)	101.51	%	97.50 - 102.00	USP 36
pH	5.46		4.50 - 6.00	USP 36
Titik Lebur	Sekitar 140, dengan penguraian		Sekitar 140, dengan penguraian	USP 36
Kelarutan dalam air	Sangat mudah larut dalam air		Sangat mudah larut dalam air	USP 36
Kelarutan dalam pelarut organik	Agak sukar larut dalam alkohol		Agak sukar larut dalam alkohol	USP 36
Identifikasi - Instrumen	Spektrum serapan UV sesuai standar Baku		Spektrum serapan UV sesuai standar Baku	USP 36

Usage Decision : DILULUSKAN
Note :

Authorization	In Charge/Position	Signature	Date/Time	Note
Prepared By	Sofia Sugiarsih, S.Si., Apt Spv. Pem. Bahan Baku			
Approve	Nurul Fatmawati, S.Farm., Apt Asman Pengawasan Mutu			

1 of 1

Gambar I.3 Sertifikat Analisis Ranitidine HCl

LAMPIRAN 1
(LANJUTAN)

SARACA LABORATORIES LIMITED

MANUFACTURERS OF BASIC DRUGS & INTERMEDIATES

CERTIFICATE OF ANALYSIS

Sl.No.	TEST	SPECIFICATION	RESULT
1.	Description	White to pale yellow, crystalline powder, hygroscopic in nature	Pale yellow crystalline powder, hygroscopic in nature
2.	Solubility	Very Soluble in water, sparingly soluble in alcohol.	Complies
3.	Identification	a. IR absorption spectrum of the sample should match with the spectrum of working standard.	Positive
		b. UV absorption spectrum: The respective absorptivity values of 10 mg/mL sample solution in water at about 229 nm and 315 nm determined on dried basis do not differ more than 3.0% when compared with a similar solution of working standard.	At 229 nm: 3.1 % At 315 nm: 3.0 %
		c. Reaction of Chlorides: Solution of sample (Stock with silver nitrate TS a white, curdy precipitate, which is insoluble in nitric acid, but is soluble in slight excess of 6 N ammonium hydroxide.	Positive
4.	Melting Point	Melts at about 140°C with decomposition.	139.0°C
5.	pH	4.2 to 6.0 (1%w/v aqueous solution)	6.08
6.	Loss on drying at 105°C (under vacuum for 3 hours)	NMT 0.75% w/w	0.38 %w/w
7.	Residue on ignition	NMT 0.1% w/w	0.018 % w/w
8.	Chromatographic Purity (By HPLC)	Ranitidine bis Compound	0.11 % w/w
		Any Other single impurity	0.03 % w/w
		Total impurities	0.14 % w/w
9.	Residual solvents	Methanol	180 ppm
		Isopropyl alcohol	380 ppm
		Chloroform	31 ppm
		Methyl isobutyl ketone	274 ppm
		Toluene	1 ppm
		Other solvents likely to be present:	
		Isopropyl chloride	1 ppm
		Isopropyl ether	ND
		Bis product	
		2-chloro(5-nitro) pyridine	1 ppm
10.	Assay on dried basis (HPLC)	97.0% w/w – 102.0% w/w	99.8 % w/w
11.	Test for Polymorphic form	The test sample IR spectrum should show the presence of peaks at 1045±2 Cm⁻¹ representing the Form-II polymorphic form of Ranitidine HCl	Positive
CUSTOMER SPECIFICATION			
12.	Color of 10%w/v aqueous solution at 450 nm	Not more than 0.250 Abs	0.041 Abs
13.	Appearance of solution	1 %w/v Solution should be clear and not more intensely colored than reference solution BY 5.	Complies
14.	Bulk density	Un-tapped	0.34 g/mL
		Tapped	0.52 g/mL

Note: ND: Not Detected, NTC: Below Detectable Limit, NMT: Not More Than, NLT: Not Less Than

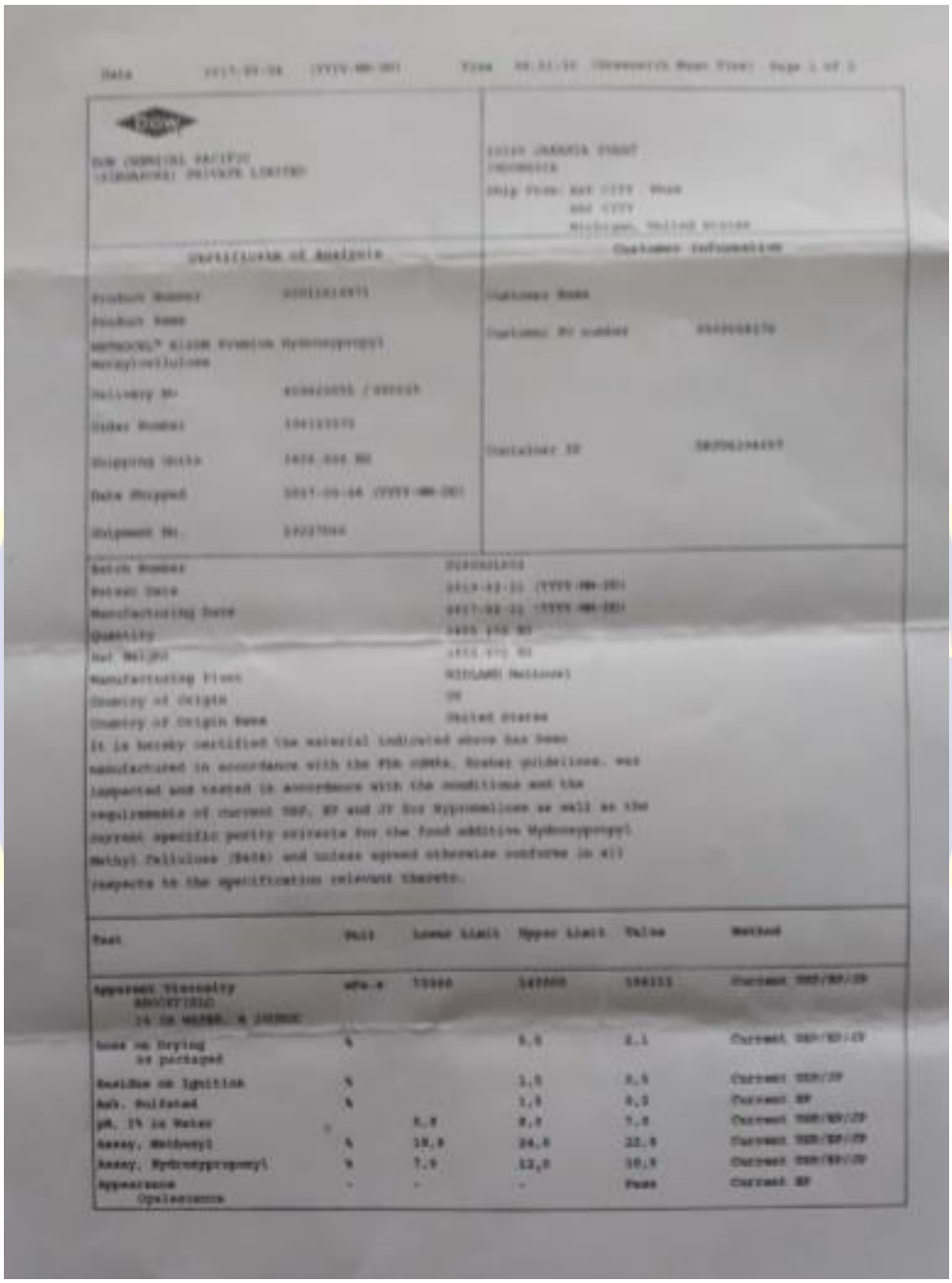
Opinion of analysis: The representative sample of above product complies/does not complies with the standards specified above.

Compiled by		Checked by		Approved by	
Date	8/8/17	Date	9/10/17	Date	11/10/17

Office Address : Plot No. 320, East Avenue, 1st Floor, Swamy Ayyappa Co-Op. Housing Society Ltd., Madhapur, Telangana State Hyderabad - 500 081, Phone : 91-40-23112680, 23112690 Fax : 91-40-23112691, E-mail : info@saraca.com

Gambar I.3 Sertifikat Analisis Ranitidin HCl

LAMPIRAN 1
(LANJUTAN)



Certificate of Analysis

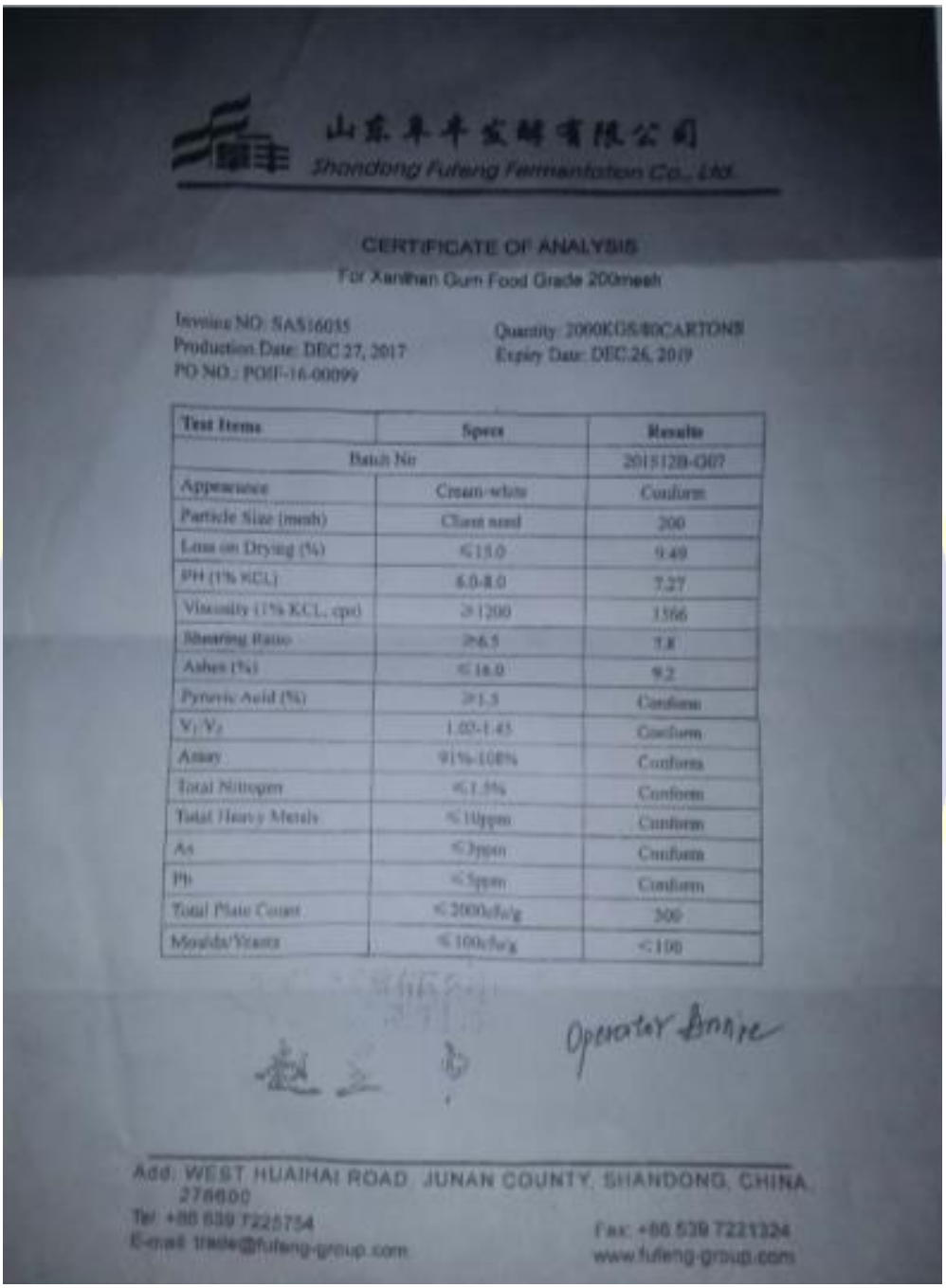
Customer Information

It is hereby certified the material indicated above has been manufactured in accordance with the FDA CGMPs, Grades 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 (Safe) and unless agreed otherwise conforms in all respects to the specification relevant thereto.

Test	Unit	Lower Limit	Upper Limit	Value	Method
Apparent Viscosity	mPa.s	75000	140000	106111	Current USP/EP/JP
Loss on Drying as packaged	%		5.0	2.1	Current USP/EP/JP
Residue on Ignition	%		1.5	0.5	Current USP/JP
Sub. Sulfated	%		1.5	0.5	Current EP
pH, 1% in Water		6.0	8.0	7.0	Current USP/EP/JP
Assay, Methoxyl	%	28.0	24.0	22.0	Current USP/EP/JP
Assay, Hydroxypropoxyl	%	7.0	12.0	10.0	Current USP/EP/JP
Appearance Opalescence	-	-	-	Pass	Current EP

Gambar I.4 Sertifikat Analisis *Hydroxypropyl Methylcellulose*

LAMPIRAN 1
(LANJUTAN)



山东阜丰发酵有限公司
Shandong Fufeng Fermentation Co., Ltd.

CERTIFICATE OF ANALYSIS
For Xanthan Gum Food Grade 200mesh

Invoice NO: SA516035
Production Date: DEC 27, 2017
PO NO.: POIF-16-00099

Quantity: 2000KGS/80CARTONS
Expiry Date: DEC 26, 2019

Test Items	Specs	Results
Batch No		20151228-007
Appearance	Cream-white	Conform
Particle Size (mesh)	Client need	200
Loss on Drying (%)	≤15.0	9.49
PH (1% KCL)	6.0-8.0	7.27
Viscosity (1% KCL, cps)	≥1200	1566
Shearing Ratio	≥6.5	7.8
Ashes (%)	≤16.0	9.2
Pyruvic Acid (%)	≥1.5	Conform
V_1/V_2	1.02-1.45	Conform
Assay	91%-108%	Conform
Total Nitrogen	≤1.5%	Conform
Total Heavy Metals	≤10ppm	Conform
As	≤2ppm	Conform
Pb	≤5ppm	Conform
Total Plate Count	≤2000cfu/g	300
Moulds/Yeasts	≤100cfu/g	<100

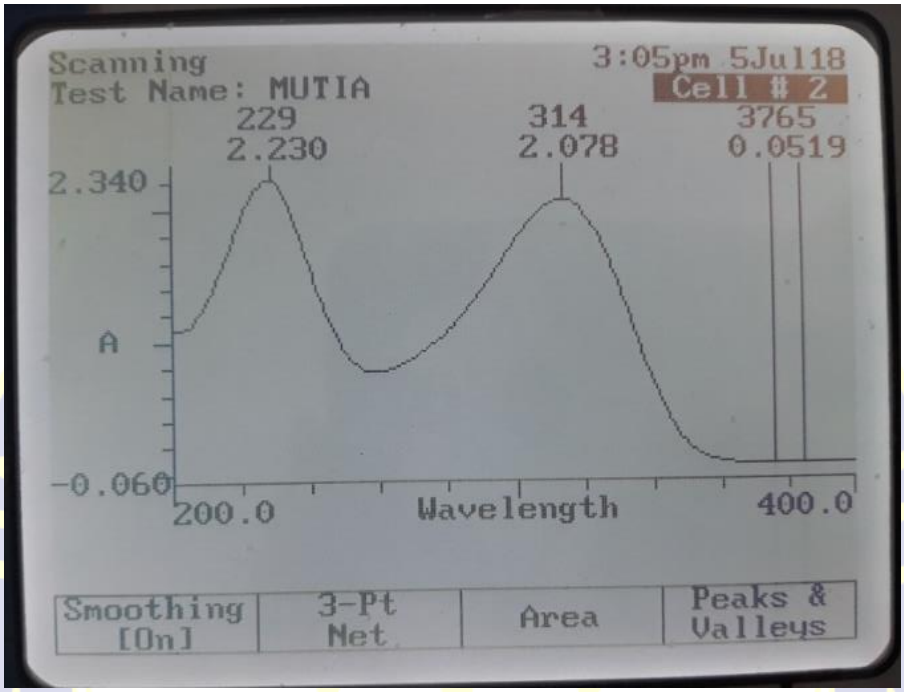
Operator Annie

Add: WEST HUAIHAI ROAD JUNAN COUNTY, SHANDONG, CHINA, 276600
Tel: +86 539 7225754
E-mail: trade@fufeng-group.com
Fax: +86 539 7221324
www.fufeng-group.com

Gambar I.5 Sertifikat Analisis Xanthan Gum

LAMPIRAN 2

HASIL IDENTIFIKASI RANITIDINE HCl



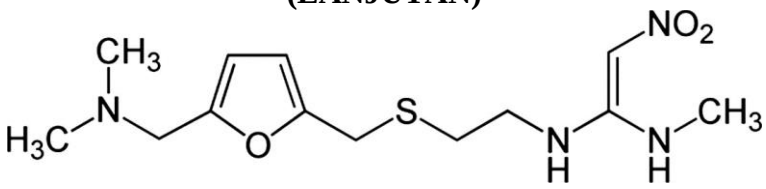
Gambar I.6 Hasil *scanning* panjang gelombang maksimum ranitidine HCl pada larutan aquadest konsentrasi 10 ppm

Tabel VII.1

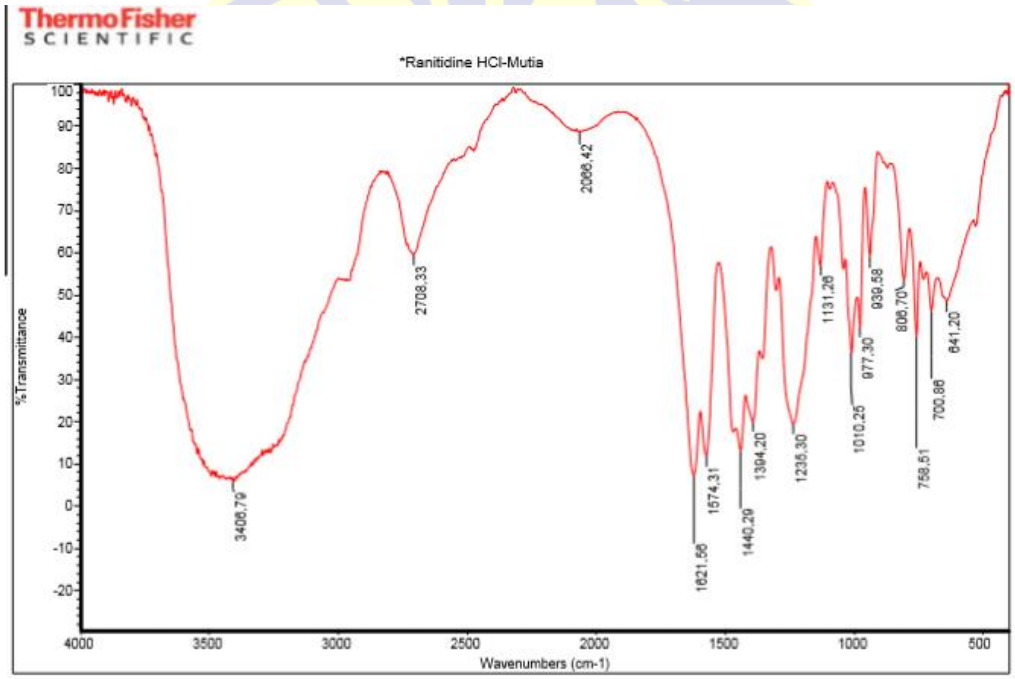
Panjang Gelombang Maksimum
Ranitidine HCl dengan Aquadest

Sumber	**Lamda Max. Ranitidine HCl**
Moffat.A.C.,2005	313 nm
Sertifikat Analisis	229 nm dan 315 nm

LAMPIRAN 2
(LANJUTAN)



Gambar I.7 Struktur Ranitidine HCl



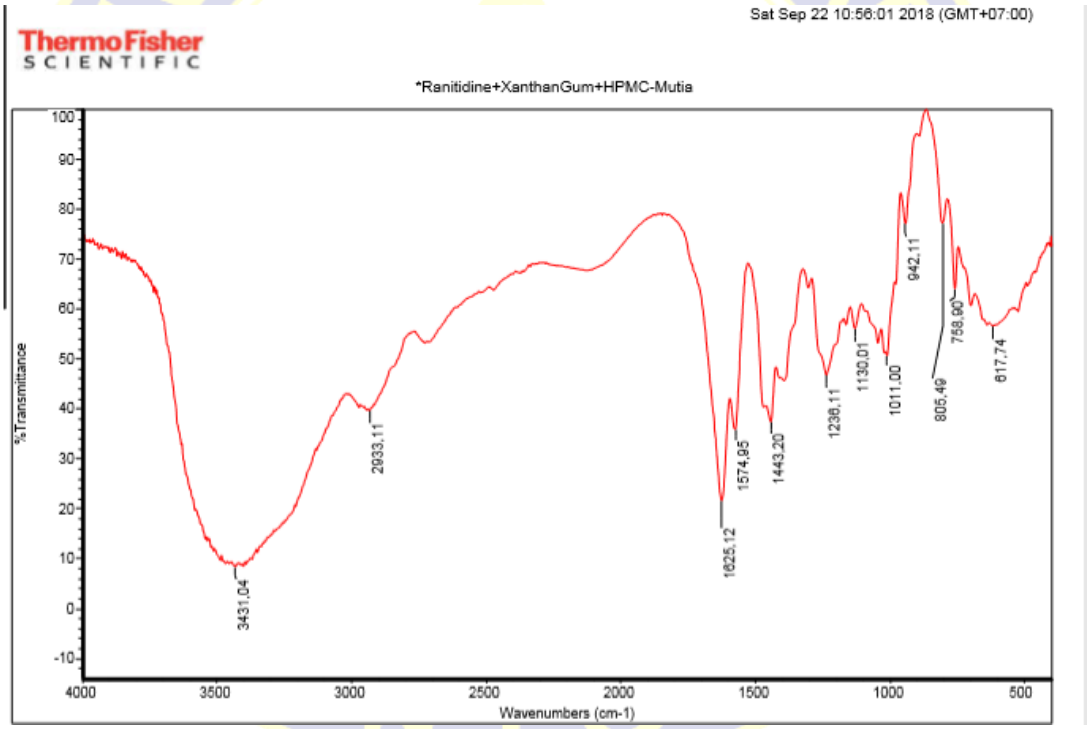
Gambar I.8 Hasil identifikasi ranitidine HCl dengan Spektrofotometer IR

LAMPIRAN 2
(LANJUTAN)

Tabel VII.2

Hasil Spektrum Spektrofotometer IR Ranitidine HCl

Gugus Fungsi	Bilangan Gelombang
C – H	1440,29
C = C	1574,31
C = C	1621,56
OH	2708,33
OH	3406,79



Gambar I.9 Hasil identifikasi kombinasi zat aktif ranitidine HCl dengan polimer Xanthan Gum dan HPMC menggunakan Spektrofotometer IR

LAMPIRAN 2
(LANJUTAN)

Tabel VII.3

Hasil Spektrum Spektrofotometer IR kombinasi zat aktif Ranitidine HCl dengan polimer xanthan gum dan HPMC

Gugus Fungsi	**Bilangan Gelombang**
C – H	1443,20
C = C	1574,31
C = C	1625,12
C – H	2933,11
OH	3431,04

LAMPIRAN 3

PERHITUNGAN PEMBUATAN LARUTAN HCl 0,1 N

Larutan HCl 0,1 N digunakan sebagai larutan dalam studi daya apung dan uji disolusi obat *gastroretentive floating* tablet ranitidine HCl.

Perhitungan :

Diketahui : Berat Ekivalen (BE) HCl = 36,46 g/mol

Berat Jenis HCl = 1,19 g/ml

% Kadar HCl pekat = 35 %

Ditanya : Volume HCl pekat yang diperlukan dalam pembuatan larutan HCl 0,1 N dalam labu takar 1000 ml.

Penyelesaian : $N = \frac{\%\ Kadar\ x\ 10\ x\ Berat\ Jenis}{Berat\ Ekivalen\ (BE)}$ x BE asam

$$N = \frac{35\%\ x\ 10\ x\ 1{,}19\ g/ml}{36{,}46\ g/mol}$$

N = 11,42 N

Volume HCl pekat yang diperlukan : $V_1.N_1 = V_2.N_2$

$V_1\ x$ 11,42 N = 1000 ml x 0,1 N

V_1 = 8,7 ml

Sehingga diperlukan 8,7 ml HCl pekat untuk membuat larutan HCl 0,1 N dalam labu takar 1000 ml.

LAMPIRAN 4

HASIL STUDI DAYA APUNG (*BUOYANCY STUDIES)*

Tabel VII.4

Hasil Studi Daya Apung (*Buoyancy Studies)*

Formula	*Lag time*	*Floating time*
F1	8 menit 35 detik	>12 jam
F2	25 menit 40 detik	>12 jam
F3	5 menit 9 detik	>12 jam
F4	-	-
F5	-	-
F6	-	-
F7	-	-
F8	-	-
F9	-	-
F10	-	-
F11	-	-
F12	-	-

LAMPIRAN 5

PERHITUNGAN FORMULASI *FLOATING* RANITIDINE HCl

1. Formulasi F1

Fase dalam (89,25%)

Total fase dalam untuk 200 tablet = 124,95 g

Ranitidine HCl = 60 g

Xanthan Gum = 25 g

HPMC = 15 g

Starch (9,65% x 700) = 13,5 g

PVP = 5 g

Avicel = 9 g

Diperoleh granul 122,50 g, kandungan lembab 2,25%

Jadi dalam 122,50 gram granul yang diperoleh mengandung ranitidine HCl sejumlah:

$$\frac{122,50}{124,95} \text{ x } 60 \text{ g} = 58,82 \text{ g}$$

Jumlah tablet yang dapat dibuat = (58,82 g/0,3 g) = 196,07 tablet

Bobot tablet = $\frac{\frac{100}{89,25} x\ (122,50) g}{196,07}$ = 0,700 = 700 mg

Fase luar (10,75%) :

Mg. stearate 0,5/89,25 x 122,50 = 0,68 g

Talk 1/89,25 x 122,50 = 1,37 g

Starch 9,65/89,25 x 122,50 = 13,5 g

LAMPIRAN 5
(LANJUTAN)

2. Formulasi F2

Fase dalam (93,5%)

Total fase dalam untuk 200 tablet = 130,90 g

Ranitidine HCl = 60 g

Xanthan Gum = 30 g

HPMC = 5 g

Starch (5% x 700) = 7 g

PVP = 5 g

Avicel = 24 g

Diperoleh granul 125,20 g, kandungan lembab 2,75%

Jadi dalam 125,20 gram granul yang diperoleh mengandung ranitidine HCl sejumlah:

$$\frac{128,45}{130,90} \text{ x } 60 \text{ g} = 58,87 \text{ g}$$

Jumlah tablet yang dapat dibuat = (58,87 g/0,3 g) = 196,23 tablet

Bobot tablet = $\frac{\frac{100}{93,5} x\ (128,45) g}{196,23}$ = 0,700 = 700 mg

Fase luar (6,5%) :

Mg. stearate 0,5/93,5 x 128,45 = 0,68 g

Talk 1/93,5 x 128,45 = 1,37 g

Starch 5/93,5 x 128,45 = 6,89 g

LAMPIRAN 5
(LANJUTAN)

3. Formulasi F3

Fase dalam (91%)

Total fase dalam untuk 200 tablet = 127,40 g

Ranitidine HCl = 60 g

Xanthan Gum = 15 g

HPMC = 25 g

Starch (7,5% x 700) = 10,5 g

PVP = 5 g

Avicel = 12 g

Diperoleh granul 127,40 g, kandungan lembab 1,75%

Jadi dalam 127,40 gam granul yang diperoleh mengandung ranitidine HCl sejumlah:

$$\frac{125,20}{127,40} \text{ x } 60 \text{ g} = 58,96 \text{ g}$$

Jumlah tablet yang dapat dibuat = (58,96 g/0,3 g) = 196,53 tablet

Bobot tablet = $\frac{\frac{100}{91} x\ (125,20) g}{196,53}$ = 0,700 = 700 mg

Fase luar (9%) :

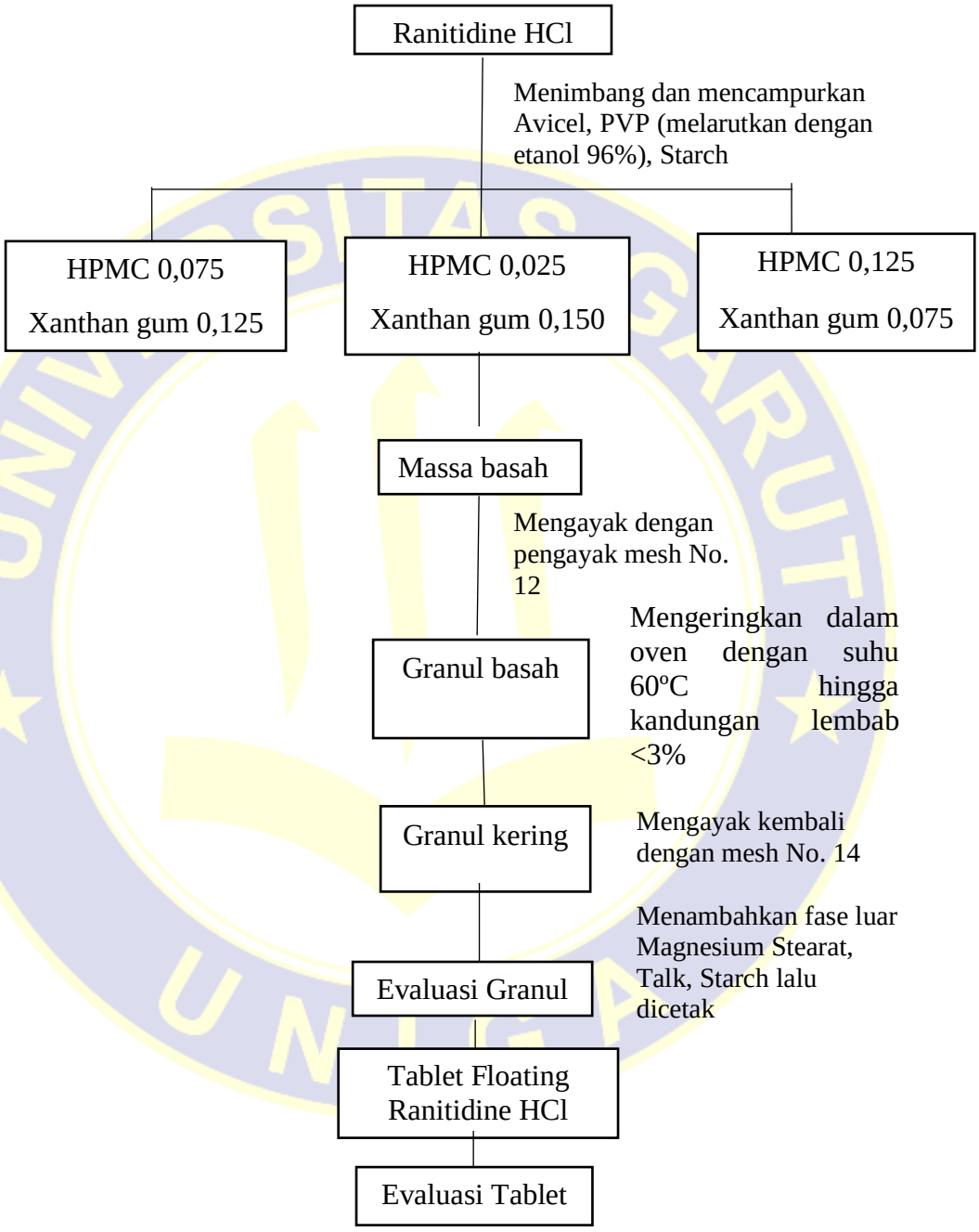
Mg. stearate 0,5/91 x 125,20 = 0,68 g

Talk 1/91x 128,45 = 1,37 g

Starch 7,5/91 x 125,20 = 10,31 g

LAMPIRAN 6

PEMBUATAN TABLET *FLOATING* RANITIDINE HCL F1, F2, F3



Gambar I.10 Skema Pembuatan Tablet *Floating* Ranitidine HCl

LAMPIRAN 7

HASIL EVALUASI GRANUL *FLOATING* RANITIDINE HCL

Tabel VII.5

Data Kandungan Air Granul (%)

Formula	Replikasi	Kadar Air (%)	Mean
F1	1	2,25	2,25
	2	2,25	
	3	2,25	
F2	1	2,75	2,75
	2	2,75	
	3	2,75	
F3	1	1,75	1,75
	2	1,75	
	3	1.75	

Tabel VII.6

Hasil Uji Sifat Alir Granul

Formula	Replikasi	Berat (g)	Volume (ml)	BJ. Nyata (g/ml)	Mean	SD	KV
F1	1	50	126	0,397	0,395	0,002	7,500
	2	50	127	0,394			
	3	50	127	0,394			
F2	1	~~50~~	144	0,347	0,348	0,001	5,400
	2	50	144	0,347			
	3	50	143	0,350			
F3	1	50	140	0,357	0,356	0,001	5,260
	2	50	141	0,355			
	3	50	140	0,357			

LAMPIRAN 7
(LANJUTAN)

Tabel VII.7

Hasil Uji Sudut Diam

Formula	Replikasi	Perlakuan	Tinggi (cm)	Diameter (cm)	Jari-jari (cm)	Sudut Diam	Mean	SD	KV
F1	1	1	2,3	11,2	5,6	22,29	22,29	0,09	0,4
		2	2,5	11	5,5	22,41			
		3	2,5	11	5,5	22,24			
	2	1	2,3	11,1	5,55	22,15	23,04	0,08	0,34
		2	2,3	11,2	5,6	22,32			
		3	2,5	10,9	5,45	24,64			
	3	1	2,5	11	5,5	24,44	23,79	0,03	0,12
		2	2,5	11	5,5	24,44			
		3	2,3	11,1	5,55	22,5			
F2	1	1	2,7	10,8	1035,4	26,56	25,91	1,13	0,04
		2	2,7	10,8	5,4	26,56			
		3	2,5	10,9	5,45	24,6			
	2	1	2,6	10,8	5,4	25,7	25,95	0,53	2,04
		2	2,7	10,8	5,4	26,56			
		3	2,6	10,9	5,45	25,59			
	3	1	2,7	10,9	5,45	26,35	26,41	0,75	2,83
		2	2,6	10,8	5,4	25,7			
		3	2,8	10,9	5,45	27,19			
F3	1	1	2,5	11	5,5	24,41	24,11	0,97	4,02
		2	2,6	11,2	5,6	24,89			
		3	2,3	10,8	5,4	23,02			
	2	1	2,6	10,8	5,4	25,7	25,84	0,22	0,85
		2	2,6	10,9	5,45	25,5			
		3	2,5	10,1	5,05	26,33			
	3	1	2,6	10	5	27,47	28,01	0,74	2,64
		2	2,7	9,8	4,9	28,85			
		3	2,6	9,9	4,95	27,71			

LAMPIRAN 7
(LANJUTAN)

Tabel VII.8

Hasil Uji Bobot Jenis Nyata Granul

Formula	Perlakuan	Berat Ganul (g)	Waktu (detik)	Sifat Alir (g/detik)	Mean	SD	KV
F1	1	50	8,88	5,631	5,603	0,028	0,499
	2	50	8,92	5,605			
	3	50	8,97	5,574			
	1	50	8,97	5,574	5,603	0,026	0,464
	2	50	8,91	5,612			
	3	50	8,89	5,624			
	1	50	8,88	5,631	5,608	0,025	0,445
	2	50	8,96	5,580			
	3	50	8,91	5,612			
F2	1	50	9,33	5,359	5,380	0,042	0,78
	2	50	9,34	5,353			
	3	50	9,21	5,429			
	1	50	9,22	5,423	5,380	0,037	0,687
	2	50	9,33	5,359			
	3	50	9,33	5,359			
	1	50	9,32	5,365	5,382	0,041	0,761
	2	50	9,34	5,353			
	3	50	9,21	5,429			
F3	1	50	9,88	5,061	5,062	0,008	0,158
	2	50	9,89	5,056			
	3	50	9,86	5,071			
	1	50	9,85	5,076	5,074	0,013	0,256
	2	50	9,88	5,061			
	3	50	9,83	5,086			
	1	50	9,86	5,071	5,068	0,016	0,315
	2	50	9,84	5,081			
	3	50	9,9	5,051			

LAMPIRAN 7
(LANJUTAN)

Tabel VII.9

Hasil Uji Bobot Jenis Mampat Granul

Formula	Replikasi	Berat (g)	Ketukan (n kali)	Volume Ketukan (ml)	Bj Mampat (g/ml)	Mean	SD	KV
F1	1	50	10	121	0,413	0,411	0,002	0,486
	2	50		122	0,410			
	3	50		122	0,410			
	1	50	500	113	0,442	0,440	0,002	0,454
	2	50		114	0,439			
	3	50		114	0,439			
F2	1	50	10	136	0,368	0,369	0,002	0,542
	2	50		136	0,368			
	3	50		135	0,370			
	1	50	500	126	0,397	0,398	0,002	0,502
	2	50		126	0,397			
	3	50		125	0,400			
F3	1	50	10	128	0,391	0,390	0,002	0,512
	2	50		129	0,388			
	3	50		128	0,391			
	1	50	500	120	0,417	0,418	0,002	0,478
	2	50		120	0,417			
	3	50		119	0,420			

LAMPIRAN 7
(LANJUTAN)

Tabel VII.10

Hasil Uji Kadar Pemampatan Granul

Formula	Replikasi	Volume (ml)	Ketukan (n kali)	Volume ketukan (ml)	Kadar Mampat (%)	Mean	SD	KV
F1	1	126	10	121	3,96	3,94	0,02	0,5
	2	127		122	3,93			
	3	127		122	3,93			
	1	126	500	113	10,31	10,26	0,05	0,48
	2	127		114	10,23			
	3	127		114	10,23			
F2	1	140	10	136	5,55	5,54	0,02	0,36
	2	141		137	5,51			
	3	141		136	5,55			
	1	140	500	126	12,5	12,47	0,05	0,4
	2	141		127	12,41			
	3	141		126	12,5			
F3	1	144	10	128	8,57	9,47	0,78	8,23
	2	145		127	9,92			
	3	144		127	9,92			
	1	144	500	120	14,28	14,21	0,06	0,42
	2	145		121	14,18			
	3	144		121	14,18			

LAMPIRAN 7
(LANJUTAN)

Tabel VII.11

Hasil Uji Kompresibilitas Granul

Formula	Replikasi	BJ. Nyata	BJ. Mampat	Indeks Kompresibilitas	Mean	SD	KV
F1	1	0,396	0,442	10,40	7,85	2,21	28,15
	2	0,398	0,426	6,57			
	3	0,398	0,426	6,57			
F2	1	0,347	0,396	12,37	7,70	4,06	57,6
	2	0,332	0,352	5,68			
	3	0,338	0,356	5,05			
F3	1	0,357	0,416	14,18	14,46	0,48	22,88
	2	0,362	0,426	15,02			
	3	0,357	0,416	14,18			

Tabel VII.12

Hasil Uji Rasio Hausner Granul

Formula	Replikasi	Kerapatan curah	Kerapatan mampat	Rasio Hausner	Mean	SD	KV
F1	1	0,396	0,442	1,116	1,086	0,026	2,170
	2	0,398	0,426	1,070			
	3	0,398	0,426	1,070			
F2	1	0,347	0,396	1,141	1,085	0,049	10,100
	2	0,332	0,352	1,060			
	3	0,338	0,356	1,053			
F3	1	0,357	0,416	1,165	1,169	0,007	4,760
	2	0,362	0,426	1,177			
	3	0,357	0,416	1,165			

LAMPIRAN 8

HASIL EVALUASI TABLET *FLOATING* RANITIDINE HCl

Tabel VII.13

Hasil Uji Keseragaman Ukuran Tablet

Tebal Tablet (mm)										
No. Tablet	D. Tablet (mm)	F1			F2			F3		
		R1	R2	R3	R1	R2	R3	R1	R2	R3
1	1,37	0,67	0,67	0,67	0,65	0,66	0,61	0,61	0,61	0,65
2	1,37	0,61	0,65	0,65	0,67	0,65	0,68	0,61	0,61	0,66
3	1,37	0,65	0,66	0,61	0,66	0,68	0,61	0,67	0,61	0,67
4	1,37	0,68	0,65	0,67	0,68	0,67	0,68	0,68	0,61	0,66
5	1,37	0,67	0,65	0,65	0,66	0,65	0,67	0,68	0,61	0,66
6	1,37	0,68	0,67	0,65	0,65	0,66	0,68	0,61	0,68	0,67
7	1,37	0,67	0,68	0,68	0,67	0,67	0,68	0,61	0,68	0,68
8	1,37	0,65	0,65	0,68	0,65	0,67	0,61	0,61	0,68	0,67
9	1,37	0,69	0,67	0,67	0,67	0,66	0,61	0,68	0,61	0,66
10	1,37	0,66	0,65	0,67	0,68	0,66	0,61	0,68	0,67	0,66
11	1,37	0,65	0,66	0,68	0,66	0,68	0,61	0,67	0,68	0,65
12	1,37	0,67	0,69	0,65	0,66	0,67	0,61	0,61	0,68	0,65
13	1,37	0,65	0,65	0,67	0,67	0,65	0,68	0,68	0,61	0,67
14	1,37	0,68	0,67	0,65	0,67	0,67	0,68	0,68	0,61	0,67
15	1,37	0,67	0,68	0,65	0,66	0,65	0,67	0,68	0,61	0,65
16	1,37	0,65	0,67	0,66	0,65	0,66	0,61	0,61	0,68	0,68
17	1,37	0,65	0,68	0,69	0,67	0,68	0,61	0,61	0,68	0,67
18	1,37	0,66	0,65	0,65	0,68	0,66	0,68	0,61	0,67	0,65
19	1,37	0,65	0,61	0,66	0,65	0,67	0,61	0,61	0,61	0,68
20	1,37	0,67	0,67	0,67	0,66	0,65	0,68	0,61	0,61	0,66
Mean	1,370	0,662	0,662	0,662	0,664	0,664	0,644	0,641	0,641	0,641
SD	0,000	0,018	0,018	0,018	0,010	0,010	0,035	0,035	0,035	0,010
KV	0,58	2,71	2,71	128,57	1,5	1,5	5,43	5,46	5,46	1,56

LAMPIRAN 8
(LANJUTAN)

Tabel VII.14

Hasil Uji Keseragaman Bobot Tablet

Bobot Tablet (mg)									
No. Tablet	F1			F2			F3		
	R1	R2	R3	R1	R2	R3	R1	R2	R3
1	670	650	700	720	690	700	700	650	690
2	670	700	700	680	700	710	710	660	690
3	680	650	680	690	680	690	660	640	680
4	680	660	700	700	690	690	660	630	690
5	670	660	700	710	690	700	650	660	690
6	670	670	700	680	680	670	640	650	690
7	660	690	690	710	690	670	700	630	690
8	660	700	690	720	720	670	680	650	680
9	660	700	690	610	730	680	670	660	680
10	680	700	690	730	700	670	680	620	660
11	660	680	690	740	690	690	690	650	680
12	700	670	700	720	710	680	700	650	670
13	680	660	680	700	720	660	650	650	690
14	670	700	700	710	700	680	680	660	670
15	660	700	680	690	690	710	660	650	680
16	660	700	680	680	660	720	660	660	680
17	700	690	690	670	680	700	650	670	680
18	700	700	690	680	710	710	680	670	660
19	650	700	700	730	700	720	690	650	670
20	640	690	700	680	690	690	700	660	690
Mean	671,00	683,50	692,50	697,50	696,00	690,50	675,50	651,00	680,50
SD	16,19	18,99	7,86	29,00	16,35	17,91	20,89	12,94	9,99
KV	2,41	2,77	1.13	4,15	2,34	2,59	3,09	1,98	1,46

LAMPIRAN 8
(LANJUTAN)

Tabel VII.15

Hasil Uji Friabilitas Tablet

Formula		Bobot awal (g)	Bobot akhir (g)	Kerapuhan (%)	Mean	SD	KV
F1	1	13,94	13,81	0,932	0,49	0,39	79,59
	2	14,7	14,67	0,204			
	3	13,02	12,97	0,348			
F2	1	14,73	14,62	0,746	0,50	0,22	44
	2	13,35	13,29	0,449			
	3	13,02	12,98	0,307			
F3	1	13,57	13,45	0,884	0,75	0,32	42,67
	2	14,24	14,1	0,983			
	3	13,02	12,97	0,384			

Tabel VII.16

Hasil Uji Friksibilitas Tablet

Formula	Replikasi	Berat Awal (g)	Berat Akhir (g)	Kerapuhan (%)	Mean	SD	KV
F1	1	13,94	13,82	0,86	0,78	0,07	8,97
	2	13,96	13,88	0,715			
	3	14,34	14,23	0,767			
F2	1	14,75	14,64	0,745	0,73	0,19	26,02
	2	13,06	12,99	0,535			
	3	13,02	12,9	0,922			
F3	1	13,76	13,64	0,872	0,85	0,08	9,41
	2	14,34	14,23	0,767			
	3	13,02	12,9	0,922			

LAMPIRAN 8
(LANJUTAN)

Tabel VII.17

Hasil Uji Kekerasan Tablet

Kekerasan Tablet (kg/cm2)									
No Tablet	F1			F2			F3		
	R1	R2	R3	R1	R2	R3	R1	R2	R3
1	8,0	6,8	8,6	7,0	9,8	8,4	6,7	6,2	6,0
2	8,6	8,0	9,0	10,0	6,0	7,0	6,6	7,2	7,4
3	7,0	8,8	8,8	10,5	6,8	8,6	6,0	7,6	6,7
4	7,8	8,6	9,0	8,0	10,0	7,2	6,7	5,2	5,0
5	6,8	6,2	6,4	8,6	7,0	6,0	5,8	7,6	6,7
6	8,2	7,0	8,0	7,4	8,0	9,0	6,7	8,2	8,0
7	7,4	7,6	6,7	7,0	7,8	8,7	6,0	7,0	6,0
8	8,0	8,0	8,0	7,0	8,0	7,0	7,7	5,2	5,0
9	7,0	8,0	7,0	7,6	8,0	6,0	7,8	8,7	7,8
10	9,0	10,2	10,0	9,0	10,0	8,8	7,8	7,4	4,7
11	10,5	10,0	10,0	9,4	8,4	4,8	6,2	5,0	6,0
12	12,0	12,0	12,3	8,0	7,0	6,2	6,0	5,6	6,5
13	12,2	12,6	6,2	8,3	8,0	7,8	7,8	6,0	5,0
14	12,5	9,0	10,0	9,5	7,8	8,7	7,0	8,7	7,8
15	9,7	7,9	8,0	9,0	10,0	10,2	7,7	7,7	7,7
16	8,6	7,0	8,0	4,0	6,0	6,4	6,0	5,0	6,0
17	7,8	8,0	8,0	4,6	4,0	4,8	5,4	4,5	5,4
18	8,0	8,7	8,7	4,8	8,4	4,8	8,0	7,0	8,0
19	7,0	12,2	12,0	9,1	9,0	7,2	5,2	5,0	7,0
20	12,5	10	9,8	10,2	9,0	8,2	6,90	6,0	6,0
Mean	8,93	8,83	8,73	7,95	7,95	7,29	6,70	6,54	6,44
SD	1,96	1,82	1,64	1,84	1,54	1,55	0,87	1,33	1,10
KV	21,89	20,66	18,81	23,13	19,36	21,29	13,00	20,37	17,02

LAMPIRAN 9

BOUYANCY STUDIES

Tabel VII.18

Hasil Studi Daya Apung Tablet *Floating* Ranitidine HCl

Formula	*Lag time*	*Floating time*
F1	8 menit 35 detik	>12 jam
F2	25 menit 40 detik	>12 jam
F3	5 menit 9 detik	>12 jam

LAMPIRAN 10
HASIL UJI DISOLUSI

Tabel VII.19

Hasil Uji Disolusi Tablet Ranitidine HCl *Floating System* Formula F1

Waktu (Jam)	Formula F1													
	Absorban Terdisolusi			Konsentrasi			Konsentrasi Koreksi			%Terdisolusi				
	1	2	3	1	2	3	1	2	3	1	2	3	Mean	SD
0,5	0,207	0,219	0,222	51,66	53,12	53,49	51,66	53,69	54,06	17,21	17,89	18,02	17,707	0,435
1	0,25	0,271	0,262	113,8	118,9	116,7	114,4	119,5	117,3	38,12	39,83	39,1	39,017	0,858
2	0,314	0,324	0,324	129,4	131,9	131,9	130	132,4	132,4	43,32	44,14	44,14	44,140	0,473
4	0,361	0,39	0,385	140,9	148	147,7	141,5	148,5	148,5	47,15	49,5	49,5	48,717	1,357
8	0,457	0,47	0,462	164,3	167,5	165,5	164,9	168	166,1	54,95	56,01	55,36	55,440	0,535
12	0,555	0,54	0,555	188,2	184,5	188,2	188,8	185,1	188,8	62,92	61,7	62,92	62,513	0,704
24	0,63	0,64	0,659	206,5	208,9	213,6	207,1	209,5	214,1	69,02	69,83	71,37	70,073	1,194

Tabel VII.20

Hasil Uji Disolusi Tablet Ranitidine HCl *Floating System* Formula F2

Waktu (Jam)	Formula F2													
	Absorban Terdisolusi			Konsentrasi			Konsentrasi Koreksi			%Terdisolusi				
	1	2	3	1	2	3	1	2	3	1	2	3	Mean	SD
0,5	0,212	0,244	0,288	52,27	56,17	61,54	52,27	56,75	62,12	17,42	18,91	20,7	19,010	1,642
1	0,327	0,326	0,337	132,6	132,3	135	133,2	132,9	135,6	44,38	44,3	45,2	44,627	0,498
2	0,397	0,378	0,348	149,7	145	137,7	150,2	145,6	138,3	50,07	48,53	46,1	46,095	2,004
4	0,426	0,427	0,437	156,7	157	159,4	157,3	157,6	160	53,43	52,51	53,33	53,090	0,505
8	0,476	0,467	0,453	168,9	166,7	163,3	169,5	167,3	163,9	56,5	55,77	54,63	55,633	0,942
12	0,55	0,58	0,579	187	194,3	194	187,6	194,9	194,6	62,51	64,95	64,87	64,110	1,386
24	0,685	0,643	0,655	219,9	209,7	210,2	220,5	210,2	210,8	73,49	70,07	70,27	71,277	1,919

LAMPIRAN 10
(LANJUTAN)

Tabel VII.21

Waktu (Jam)	Formula F3													
	Absorban Terdisolusi			Konsentrasi			Konsentrasi Koreksi			%Terdisolusi				
	1	2	3	1	2	3	1	2	3	1	2	3	Mean	SD
0,5	0,211	0,236	0,218	52,15	55,2	53	52,15	55,774	53,58	17,38	18,59	17,86	17,943	0,609
1	0,263	0,29	0,29	117	123,6	123,6	117,6	124,14	124,1	39,18	41,38	41,38	40,647	1,270
2	0,316	0,349	0,345	129,9	138	137	130,5	138,53	137,6	43,49	46,17	45,85	45,850	1,464
4	0,441	0,404	0,44	160,4	151,4	160,1	161	151,94	160,7	53,65	50,64	53,57	52,620	1,715
8	0,461	0,47	0,499	165,3	167,5	174,5	165,8	168,04	175,1	55,28	56,01	58,37	56,553	1,615
12	0,57	0,577	0,535	191,9	193,6	183,3	192,4	194,14	183,9	64,14	64,71	61,29	63,380	1,832
24	0,605	0,675	0,699	200,4	217,5	223,3	201	218,04	223,9	66,98	72,68	74,63	71,430	3,975

Hasil Uji Disolusi Tablet Ranitidine HCl *Floating System* Formula F3

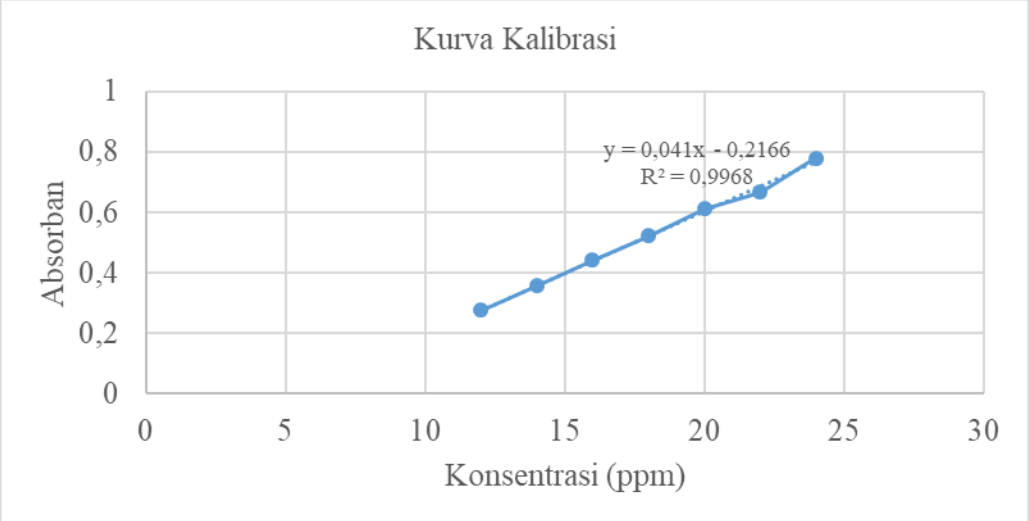
LAMPIRAN 11

KURVA KALIBRASI RANITIDINE HCl DENGAN METODE SPEKTROFOTOMETRI

Tabel VII.22

Hasil Pengukuran Absorbansi Ranitidine HCl

Konsentrasi (ppm)	Absorban
12	0,277
14	0,356
16	0,442
18	0,522
20	0,611
22	0,666
24	0,78



Gambar I.11 Kurva Kalibrasi Ranitidine HCl

LAMPIRAN 12

VERIFIKASI METODE SPEKTROFOTOMETRI UV

Tabel VII.23

Hasil Pengukuran Uji Presisi Spektrofotometer UV

Konsentrasi (ppm)	Absorbansi	X	X^2
18	0,516	17,86	318,97
18	0,512	17,77	315,77
18	0,529	18,18	330,51
18	0,532	18,25	333,06
18	0,519	17,94	321,84
Jumlah	2,608	90	1620,15

Harga serapan rata-rata = $\frac{\Sigma x}{n}$ = 18

Nilai SD = $\frac{n\Sigma x2-(\Sigma x)2}{n\,(n-1)}$ = 0,0375

Nilai RSD = $\frac{SD}{X}$ x 100% = 0,0416 %

Ketelitian alat = 100% - $\frac{SD}{x}$ = 99,9584 %

Tabel VII.24

Hasil Pengukuran Uji Akurasi Spektrofotometer UV

Penambahan Baku (ppm)	Absorban	Konsentrasi Total Sampel (ppm)	Konsentrasi sampel (ppm)	Standar yang ditambahkan (ppm)	% Recovery
10	0,343	24,84	13,64	10	112
	0,345	27,14	13,69	12	112,083
	0,342	28,61	13,62	14	107,071

LAMPIRAN 12
(LANJUTAN)

Tabel VII.25

Hasil Pengukuran Uji Limit Deteksi Spektrofotometer UV

X_1	Y	Y_i	$Y - Y_i$	$(Y - Y_i)^2$
12	0,277	0,275	0,0016	0,00000256
14	0,356	0,357	0,0014	0,00000196
16	0,442	0,439	0,0026	0,00000676
18	0,522	0,521	0,006	0,000036
20	0,611	0,603	0,0076	0,00005776
22	0,666	0,685	-0,0194	0,00037636
24	0,780	0,767	0,0126	0,00015876
Jumlah	3,654	3,649	0,7172	0,00064016

$S\frac{y}{x} = \sqrt{\frac{\Sigma(y-yi)2}{n-2}} = 0,0113$

$Y_{BD} = 3S\frac{y}{x} + a = 1,3780$

$X_{BD} = Y_{BD} - a/b = 2,7560$

LAMPIRAN 13

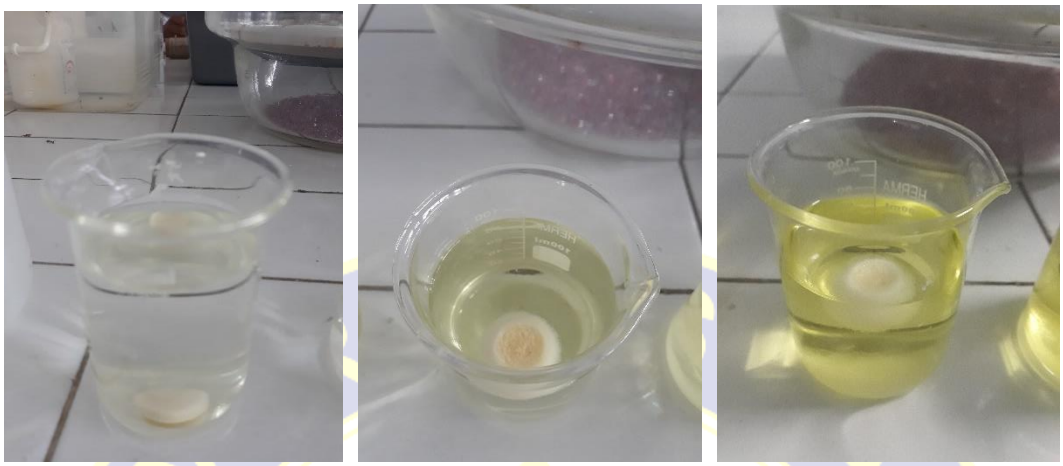
GAMBAR TABLET *FLOATING* RANITIDINE HCl

Gambar I.12 Gambar *Floating* Tablet Ranitidine HCl

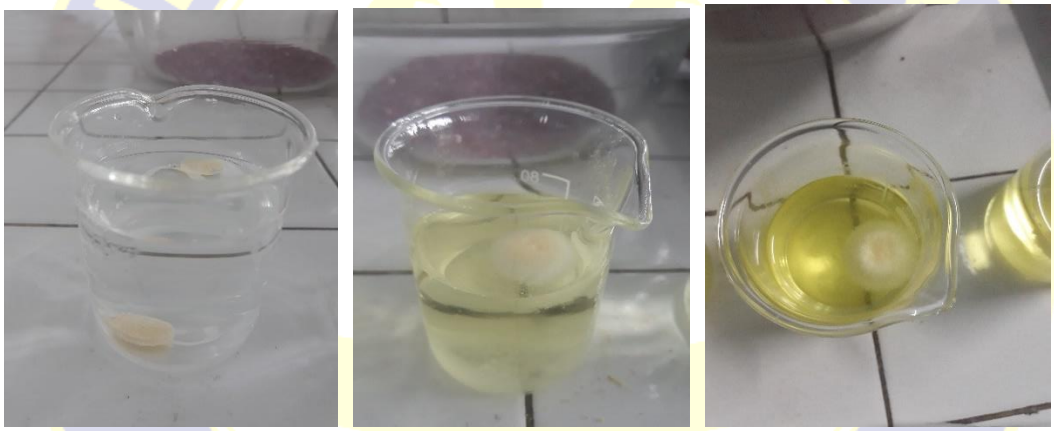
Gambar I.12 Gambar *Floating* Tablet Ranitidine HCl

LAMPIRAN 14

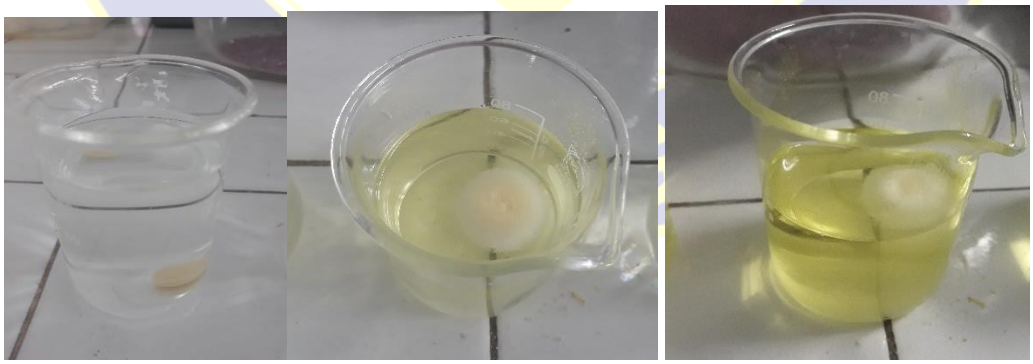
GAMBAR HASIL DAYA APUNG TABLET *FLOATING* RANITIDINE HCl



Gambar I.13 Tablet *Floating* Ranitidine HCl Formula F1



Gambar I.13 Tablet *Floating* Ranitidine HCl Formula F2



Gambar I.13 Tablet *Floating* Ranitidine HCl Formula F3