

Lampiran 1. Pernyataan Keaslian Tulisan**PERNYATAAN KEASLIAN TULISAN**

Saya yang bertanda tangan di bawah ini :

Nama : Isnavira Marina Yunita

NIM : 105070500111038

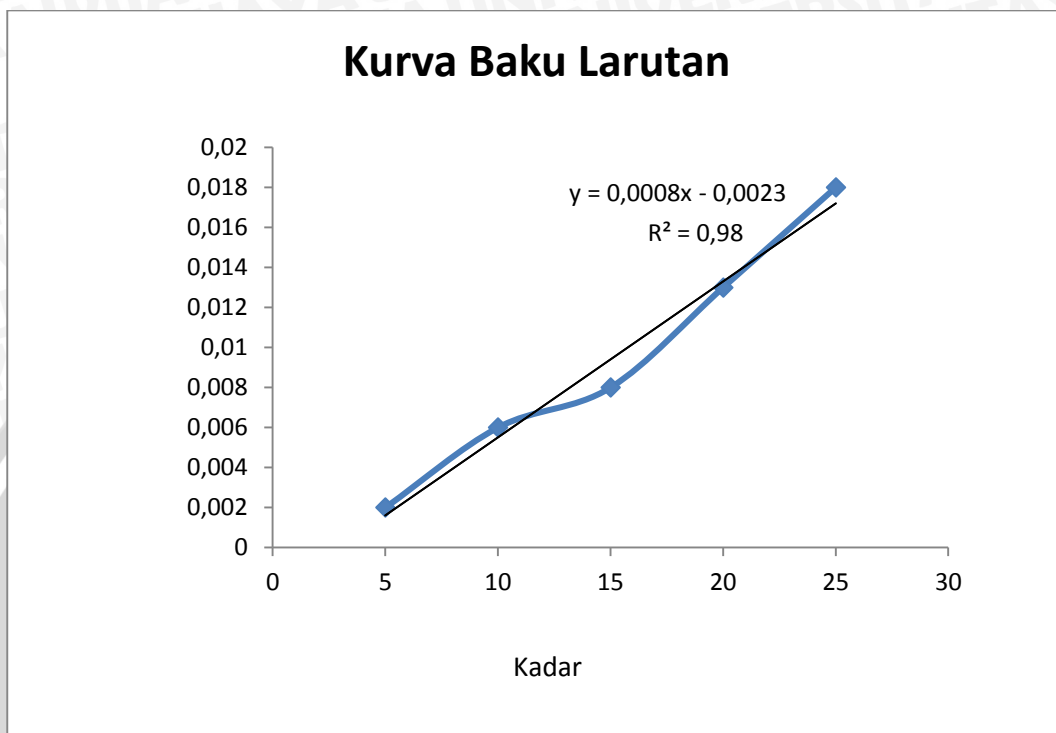
Program Studi : Program Studi Farmasi Fakultas Kedokteran Universitas
Brawijaya

Menyatakan dengan sebenarnya bahwa Tugas Akhir yang saya tulis ini benar-benar hasil karya sendiri, bukan merupakan pengambilalihan tulisan atau pikiran orang lain yang saya akui sebagai tulisan atau pikiran saya sendiri. Apabila dikemudian hari dapat dibuktikan bahwa Tugas Akhir ini adalah hasil jiplakan, maka saya bersedia menerima sanksi atas perbuatan tersebut.

Malang, 25 Agustus 2014

Isnavira Marina Yunita
105070500111038

Lampiran 2. Hasil Persamaan Kurva Baku



Lampiran 3. Nilai absorbansi dan contoh perhitungan homogenitas massa cetak F1 dan F2

| Absorbansi Homogenitas Massa Cetak | | | | | | |
|------------------------------------|-----------|--------|-------|-----------|--------|-------|
| Replikasi | Formula 1 | | | Formula 2 | | |
| | Atas | Tengah | Bawah | Atas | Tengah | Bawah |
| 1 | 0.010 | 0.009 | 0.009 | 0.011 | 0.010 | 0.011 |
| 2 | 0.010 | 0.009 | 0.009 | 0.009 | 0.010 | 0.010 |
| 3 | 0.008 | 0.010 | 0.010 | 0.009 | 0.009 | 0.008 |

Contoh perhitungan kadar metronidazol dalam sampel:

Nilai absorbansi: 0.01

Persamaan kurva baku: $y = 0.0008x - 0.0023$

Pengenceran yang dilakukan: 33.33 kali

$y = 0.0008x - 0.0023$

$0.01 = 0.0008x - 0.0023$

$0.0123 = 0.0008x$

$x = 15.375 \text{ ppm}$

Konsentrasi sebenarnya : $15.375 \text{ ppm} \times 33.33 = 512.45 \text{ ppm}$

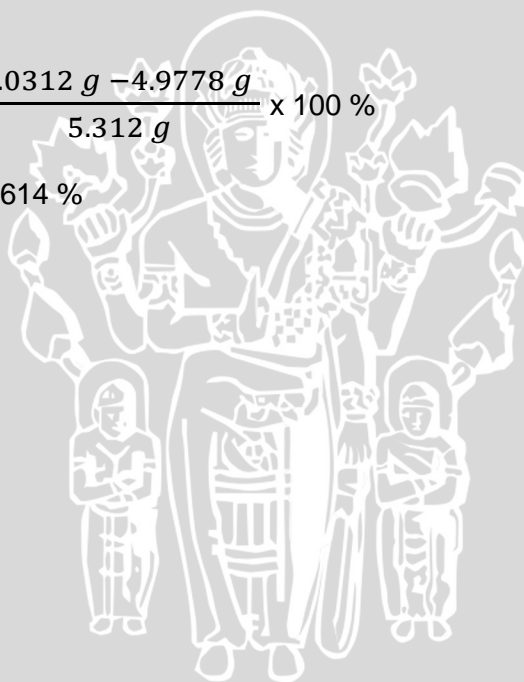
Kadar dalam sampel : $\frac{512.45 \text{ ppm}}{500 \text{ ppm}} \times 100 \% = 102.49 \%$

Lampiran 4. Perhitungan Kerapuhan Tablet

| Formula | Replikasi | Wo (g) | Wt (g) |
|-----------|-----------|--------|--------|
| Formula 1 | 1 | 5.0312 | 4.9778 |
| | 2 | 5.0121 | 4.9590 |
| | 3 | 5.0085 | 4.9465 |
| Formula 2 | 1 | 5.1300 | 5.0725 |
| | 2 | 5.1528 | 5.0864 |
| | 3 | 5.1585 | 5.1038 |

Contoh perhitungan:

$$\frac{W_o - W_t}{W_o} \times 100 \% = \frac{5.0312 \text{ g} - 4.9778 \text{ g}}{5.312 \text{ g}} \times 100 \%$$
$$= 1.0614 \%$$



Lampiran 5. Nilai absorbansi dan contoh perhitungan disolusi F1 dan F2

| Nilai Absorbansi | |
|------------------|-----------|
| Formula 1 | Formula 2 |
| 0.084 | 0.092 |
| 0.086 | 0.084 |
| 0.082 | 0.091 |
| 0.091 | 0.108 |
| 0.091 | 0.083 |
| 0.077 | 0.084 |

Contoh perhitungan:

Nilai absorbansi: 0.084

Persamaan kurva baku: $y = 0.0008x - 0.0023$

$y = 0.0008x - 0.0023$

$0.084 = 0.0008x - 0.0023$

$0.0863 = 0.0008x$

$x = 107.875 \mu\text{g/ml}$

Terdisolusi dalam 650 ml = $650 \text{ ml} \times 107.875 \mu\text{g/ml} = 70118.75 \mu\text{g} = 70.12 \text{ mg}$

% kadar terdisolusi = $\frac{70.12 \text{ mg}}{100 \text{ mg}} \times 100 \% = 70.12 \%$

Lampiran 6. Hasil uji dan perhitungan daya mengembang tablet

| Waktu (menit) | Replikasi | Formula 1 | | Formula 2 | |
|---------------|-----------|-----------|--------|-----------|--------|
| | | Wo (g) | Wt (g) | Wo | Wt |
| 15 | 1 | 0.5025 | 2.3748 | 0.5122 | 2.0300 |
| | 2 | 0.4982 | 2.3738 | 0.5135 | 2.0847 |
| | 3 | 0.5003 | 2.3742 | 0.5085 | 2.0332 |
| 30 | 1 | 0.4946 | 2.5465 | 0.5151 | 2.3015 |
| | 2 | 0.5038 | 2.5521 | 0.5140 | 2.3905 |
| | 3 | 0.5021 | 2.5501 | 0.5029 | 2.2870 |
| 60 | 1 | 0.5024 | 2.7701 | 0.5106 | 2.4993 |
| | 2 | 0.5052 | 2.9940 | 0.5028 | 2.4930 |
| | 3 | 0.5032 | 2.8850 | 0.5121 | 2.5150 |
| 120 | 1 | 0.5099 | 2.7418 | 0.5159 | 2.6680 |
| | 2 | 0.5038 | 2.6134 | 0.5125 | 2.7435 |
| | 3 | 0.5087 | 2.7254 | 0.5099 | 2.6560 |
| 240 | 1 | 0.4987 | 2.4768 | 0.5118 | 2.4251 |
| | 2 | 0.5025 | 2.5063 | 0.5092 | 2.4199 |
| | 3 | 0.5042 | 2.5575 | 0.5135 | 2.4652 |

Contoh perhitungan:

$$\frac{Wt - W_o}{W_o} = \frac{2.3748 - 0.5025}{0.5025} = 3.74$$

Lampiran 7. Nilai absorbansi dan perhitungan penetapan kadar

| Nilai Absorbansi | |
|------------------|-----------|
| Formula 1 | Formula 2 |
| 0.010 | 0.009 |
| 0.010 | 0.010 |
| 0.009 | 0.011 |

Contoh perhitungan kadar metronidazol dalam sampel:

Nilai absorbansi: 0.01

Persamaan kurva baku: $y = 0.0008x - 0.0023$

Pengenceran yang dilakukan: 33.33 kali

$y = 0.0008x - 0.0023$

$0.02 = 0.0008x - 0.0023$

$0.0123 = 0.0008x$

$x = 15.375 \text{ ppm}$

Konsentrasi sebenarnya : $15.375 \text{ ppm} \times 33.33 = 512.45 \text{ ppm}$

Kadar dalam sampel : $\frac{512.45 \text{ ppm}}{500 \text{ ppm}} \times 100\% = 102.49\%$

Lampiran 8. Hasil uji SPSS Laju alir

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|---------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Laju Alir | F1 | .297 | 3 | . | .917 | 3 | .441 |
| | F2 | .253 | 3 | . | .964 | 3 | .637 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Laju Alir |
|--------------------------------|---------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 6.000 |
| Z | -1.964 |
| Asymp. Sig. (2-tailed) | .050 |
| Exact Sig. [2*(1-tailed Sig.)] | .100(a) |

a Not corrected for ties.

b Grouping Variable: Formula

Lampiran 9. Hasil uji SPSS homogenitas massa cetak

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|-----------------|---------|-----------------------|----|---------|--------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Homogenitas | F1 | .269 | 9 | .059 | .808 | 9 | .025 |
| | F2 | .192 | 9 | .200(*) | .916 | 9 | .364 |

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Homogenitas |
|--------------------------------|-----------------|
| Mann-Whitney U | 30.500 |
| Wilcoxon W | 75.500 |
| Z | -.930 |
| Asymp. Sig. (2-tailed) | .352 |
| Exact Sig. [2*(1-tailed Sig.)] | .387(a) |

a Not corrected for ties.

b Grouping Variable: Formula

Lampiran 10. Hasil uji SPSS keseragaman Bobot

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|-----------------------|---------|-----------------------|----|---------|---------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Keseragaman Bobot | F1 | .134 | 20 | .200(*) | .972 | 20 | .804 |
| | F2 | .107 | 20 | .200(*) | .967 | 20 | .695 |

* This is a lower bound of the true significance.
 a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Keseragaman Bobot |
|--------------------------------|-----------------------|
| Mann-Whitney U | 26.500 |
| Wilcoxon W | 236.500 |
| Z | -4.694 |
| Asymp. Sig. (2-tailed) | .000 |
| Exact Sig. [2*(1-tailed Sig.)] | .000(a) |

a Not corrected for ties.
 b Grouping Variable: Formula

Lampiran 11. Hasil uji SPSS keseragaman ukuran

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Keseragaman Ukuran | F1 | .284 | 20 | .000 | .773 | 20 | .000 |
| | F2 | .266 | 20 | .001 | .855 | 20 | .006 |

a. Lilliefors Significance Correction

Test Statistics(b)

| | Uji Keseragaman Ukuran |
|--------------------------------|------------------------|
| Mann-Whitney U | 186.500 |
| Wilcoxon W | 396.500 |
| Z | -.400 |
| Asymp. Sig. (2-tailed) | .689 |
| Exact Sig. [2*(1-tailed Sig.)] | .718(a) |

a. Not corrected for ties.

b. Grouping Variable: Formula

Lampiran 12. Hasil uji SPSS kekerasan tablet

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|---------------|---------|-----------------------|----|---------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Kekerasan | F1 | .124 | 10 | .200(*) | .982 | 10 | .973 |
| | F2 | .287 | 10 | .019 | .899 | 10 | .212 |

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Kekerasan |
|--------------------------------|---------------|
| Mann-Whitney U | 45.000 |
| Wilcoxon W | 100.000 |
| Z | -.382 |
| Asymp. Sig. (2-tailed) | .703 |
| Exact Sig. [2*(1-tailed Sig.)] | .739(a) |

a Not corrected for ties.

b Grouping Variable: Formula

Lampiran 13. Hasil uji SPSS kerapuhan tablet

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|---------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Kerapuhan | F1 | .382 | 3 | . | .758 | 3 | .019 |
| | F2 | .285 | 3 | . | .931 | 3 | .494 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Kerapuhan |
|--------------------------------|---------------|
| Mann-Whitney U | 3.000 |
| Wilcoxon W | 9.000 |
| Z | -.655 |
| Asymp. Sig. (2-tailed) | .513 |
| Exact Sig. [2*(1-tailed Sig.)] | .700(a) |

a Not corrected for ties.

b Grouping Variable: Formula



Lampiran 14. Hasil uji SPSS waktu hancur

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Waktu Hancur | F1 | .407 | 6 | .002 | .640 | 6 | .001 |
| | F2 | .407 | 6 | .002 | .640 | 6 | .001 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Waktu Hancur |
|--------------------------------|------------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 21.000 |
| Z | -3.000 |
| Asymp. Sig. (2-tailed) | .003 |
| Exact Sig. [2*(1-tailed Sig.)] | .002(a) |

a Not corrected for ties.

b Grouping Variable: Formula

Lampiran 15. Hasil uji SPSS disolusi

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|--------------|---------|-----------------------|----|---------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Disolusi | F1 | .193 | 6 | .200(*) | .933 | 6 | .603 |
| | F2 | .264 | 6 | .200(*) | .798 | 6 | .056 |

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Disolusi |
|--------------------------------|--------------|
| Mann-Whitney U | 12.000 |
| Wilcoxon W | 33.000 |
| Z | -.974 |
| Asymp. Sig. (2-tailed) | .330 |
| Exact Sig. [2*(1-tailed Sig.)] | .394(a) |

a Not corrected for ties.

b Grouping Variable: Formula



Lampiran 16. Hasil uji SPSS mukoadhesif

Tests of Normality(a,b)

- a Uji Mukoadhesif is constant when Formula = F1. It has been omitted.
- b Uji Mukoadhesif is constant when Formula = F2. It has been omitted.

Test Statistics(b)

| | Uji Homogenitas |
|--------------------------------|-----------------|
| Mann-Whitney U | 30.500 |
| Wilcoxon W | 75.500 |
| Z | -.930 |
| Asymp. Sig. (2-tailed) | .352 |
| Exact Sig. [2*(1-tailed Sig.)] | .387(a) |

- a Not corrected for ties.
- b Grouping Variable: Formula

Lampiran 17. Hasil uji SPSS daya mengembang tablet

1. Daya mengembang 15 menit

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Daya Mengembang 15 | F1 | .328 | 3 | . | .871 | 3 | .298 |
| | F2 | .269 | 3 | . | .949 | 3 | .567 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Daya Mengembang 15 |
|--------------------------------|------------------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 6.000 |
| Z | -1.964 |
| Asymp. Sig. (2-tailed) | .050 |
| Exact Sig. [2*(1-tailed Sig.)] | .100(a) |

a Not corrected for ties.

b Grouping Variable: Formula

2. Daya mengembang 30 menit

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Daya Mengembang 30 | F1 | .343 | 3 | . | .842 | 3 | .220 |
| | F2 | .196 | 3 | . | .996 | 3 | .878 |

a Lilliefors Significance Correction



Test Statistics(b)

| | Uji Daya Mengembang 30 |
|--------------------------------|------------------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 6.000 |
| Z | -1.964 |
| Asymp. Sig. (2-tailed) | .050 |
| Exact Sig. [2*(1-tailed Sig.)] | .100(a) |

a Not corrected for ties.

b Grouping Variable: Formula

3. Daya mengembang 60 menit.

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Daya Mengembang 60 | F1 | .179 | 3 | . | .999 | 3 | .948 |
| | F2 | .276 | 3 | . | .942 | 3 | .537 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Daya Mengembang 60 |
|--------------------------------|------------------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 6.000 |
| Z | -1.964 |
| Asymp. Sig. (2-tailed) | .050 |
| Exact Sig. [2*(1-tailed Sig.)] | .100(a) |

a Not corrected for ties.

b Grouping Variable: Formula



4. Daya mengembang 120 menit

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|-------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Daya Mengembang 120 | F1 | .351 | 3 | . | .828 | 3 | .183 |
| | F2 | .304 | 3 | . | .907 | 3 | .407 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Daya Mengembang 120 |
|--------------------------------|-------------------------|
| Mann-Whitney U | 2.000 |
| Wilcoxon W | 8.000 |
| Z | -1.091 |
| Asymp. Sig. (2-tailed) | .275 |
| Exact Sig. [2*(1-tailed Sig.)] | .400(a) |

a Not corrected for ties.

b Grouping Variable: Formula

5. Daya mengembang 240 menit

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|-------------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statistic | df | Sig. | Statistic | df | Sig. |
| Uji Daya Mengembang 240 | F1 | .314 | 3 | . | .893 | 3 | .363 |
| | F2 | .328 | 3 | . | .871 | 3 | .298 |

a Lilliefors Significance Correction

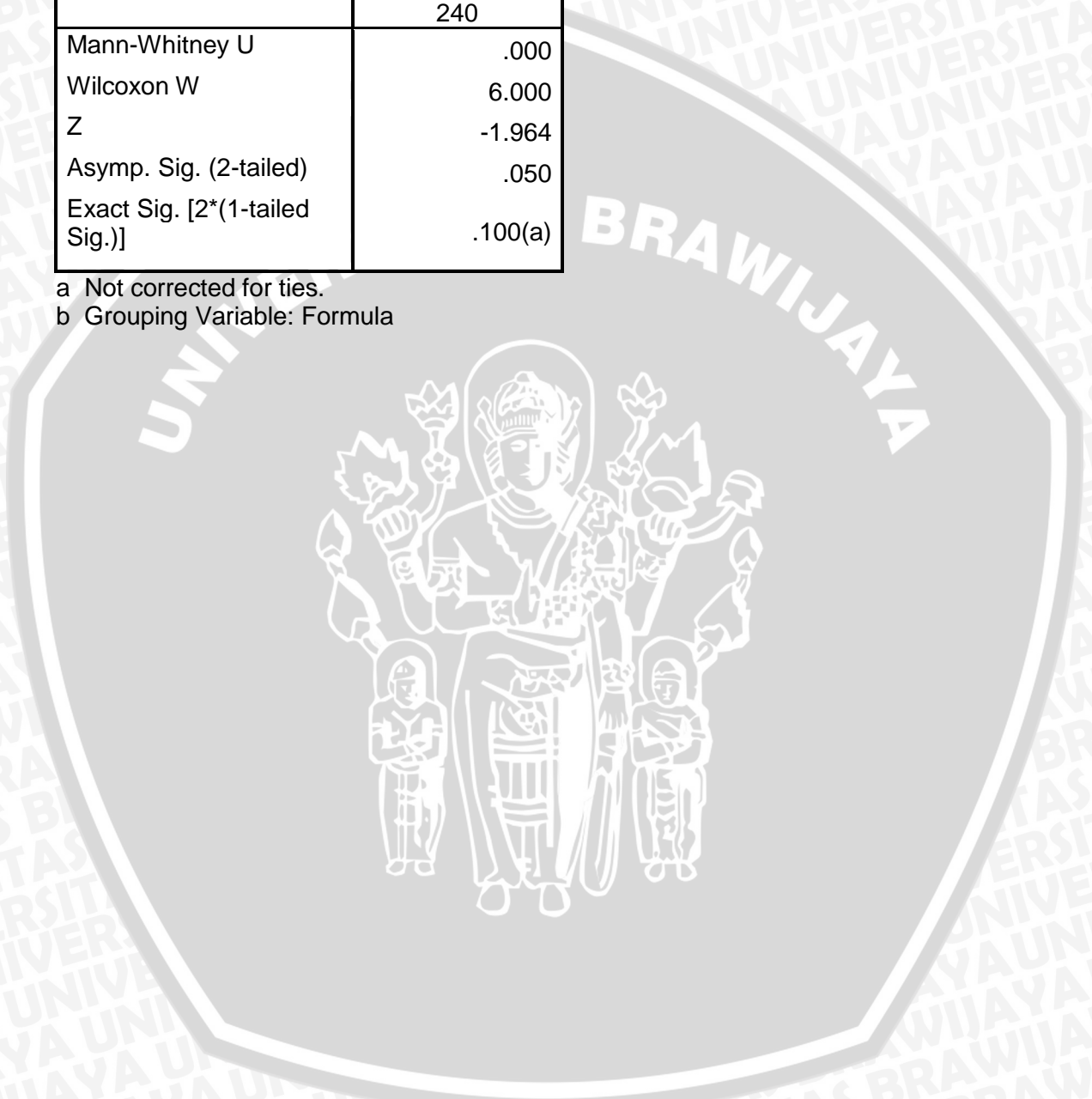


Test Statistics(b)

| | Uji Daya Mengembang 240 |
|--------------------------------|----------------------------|
| Mann-Whitney U | .000 |
| Wilcoxon W | 6.000 |
| Z | -1.964 |
| Asymp. Sig. (2-tailed) | .050 |
| Exact Sig. [2*(1-tailed Sig.)] | .100(a) |

a Not corrected for ties.

b Grouping Variable: Formula



Lampiran 18. Hasil uji SPSS penetapan kadar

Tests of Normality

| | Formula | Kolmogorov-Smirnov(a) | | | Shapiro-Wilk | | |
|---------------------|---------|-----------------------|----|------|--------------|----|------|
| | | Statisti c | df | Sig. | Statisti c | df | Sig. |
| Uji Penetapan Kadar | F1 | .385 | 3 | . | .750 | 3 | .000 |
| | F2 | .385 | 3 | . | .750 | 3 | .000 |

a Lilliefors Significance Correction

Test Statistics(b)

| | Uji Penetapan Kadar |
|--------------------------------|---------------------|
| Mann-Whitney U | 4.000 |
| Wilcoxon W | 10.000 |
| Z | -.236 |
| Asymp. Sig. (2-tailed) | .814 |
| Exact Sig. [2*(1-tailed Sig.)] | 1.000(a) |

a Not corrected for ties.

b Grouping Variable: Formula

Lampiran 19. Gambar daya mengembang tablet F1 dan F2

1. Daya mengembang 15 menit



F1



F2

2. Daya mengembang 30 menit



F1



F2

3. Daya mengembang 60 menit



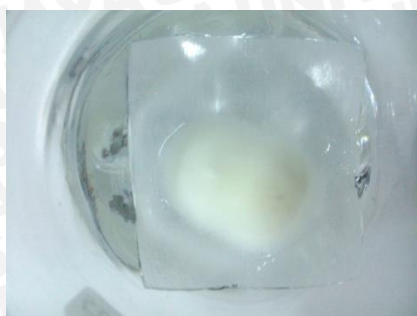
F1



F2



4. Daya mengembang 120 menit



F1



F2

5. Daya mengembang 240 menit



F1



F2

Lampiran 20. Gambar uji mukoadhesif tablet



LAMPIRAN 21. KETERANGAN KELAIKAN ETIK



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
THE MINISTRY OF EDUCATION AND CULTURE
FAKULTAS KEDOKTERAN UNIVERSITAS BRAWIJAYA
FACULTY OF MEDICINE UNIVERSITY OF BRAWIJAYA
KOMISI ETIK PENELITIAN KESEHATAN
HEALTH RESEARCH ETHICS COMMITTEE
Jalan Veteran Malang – 65145
Telp / Fax (62) 341 - 553930

KETERANGAN KELAIKAN ETIK
(“ETHICAL CLEARANCE”)

No. 344 / EC / KEPK – S1 – FARM / 05 / 2014

KOMISI ETIK PENELITIAN KESEHATAN FAKULTAS KEDOKTERAN UNIVERSITAS BRAWIJAYA, SETELAH MEMPELAJARI DENGAN SEKSAMA RANCANGAN PENELITIAN YANG DIUSULKAN, DENGAN INI MENYATAKAN BAHWA PENELITIAN DENGAN

JUDUL : *Optimasi Diluent terhadap Karakteristik Fisik dan Daya Adhesi Tablet Vaginal Ketokonazol Menggunakan Microcrystalline Cellulose dan Dibasic Calcium Phosphate*

PENELITI UTAMA : Isnavira Marina Yunita

UNIT / LEMBAGA : S1 Farmasi - Fakultas Kedokteran - Universitas Brawijaya Malang

TEMPAT PENELITIAN : Laboratorium Farmasetik, Fakultas Farmasi, Universitas Surabaya

DINYATAKAN LAIK ETIK.

Malang, 28 MAY 2014



Prof. Dr. dr. Teguh W. Sardjono, DTM&H, MSc, SpPark
NIP. 19520410 198002 1 001

Catatan :

Keterangan Laik Etik Ini Bertaku 1 (Satu) Tahun Sejak Tanggal Dikeluarkan Pada Akhir Penelitian, Laporan Pelaksanaan Penelitian Harus Diserahkan Kepada KEPK-FKUB Dalam Bentuk Soft Copy. Jika Ada Perubahan Protokol Dan / Atau Perpanjangan Penelitian, Harus Mengajukan Kembali Permohonan Kajian Etik Penelitian (Amandemen Protokol)