# BAB V

# KESIMPULAN DAN SARAN

## A. Kesimpulan

Berdasarkan hasil penelitian dapat disimpulkan bahwa :

1. Mutu fisik dan profil disolusi dari sediaan tablet prednison merk dagang dan generik memenuhi persyaratan standart kontrol kualitas tablet yang baik.
2. Sediaan tablet prednison merk dagang dan generik menghasilkan profil disolusi yang mirip yang ditunjukkan dengan nilai F2 > 50, yaitu produk ODB – OGD yaitu 73.17, OGD – OGE yaitu 57.95, OGC – OGD yaitu 54.63, ODB – OGE yaitu 52.53, OGC – OGE yaitu 51.91,.

## B. Saran

Saran dari penelitian ini adalah :

1. Tablet prednison generik memenuhi persyaratan standart yang sudah ditetapkan sehingga memiliki kualitas yang tidak jauh berbeda dari tablet prednison merk dagang, tidak ada salahnya mulai beralih dengan menggunakan tablet prednison generik yang harganya lebih terjangkau.
2. Perlu dilakukan penelitian uji disolusi terbanding tablet lain selain prednison merk dagang dan generik sehingga masyarakat dapat membandingkan kualitas antara obat merk dagang dan generik tidak berbeda.

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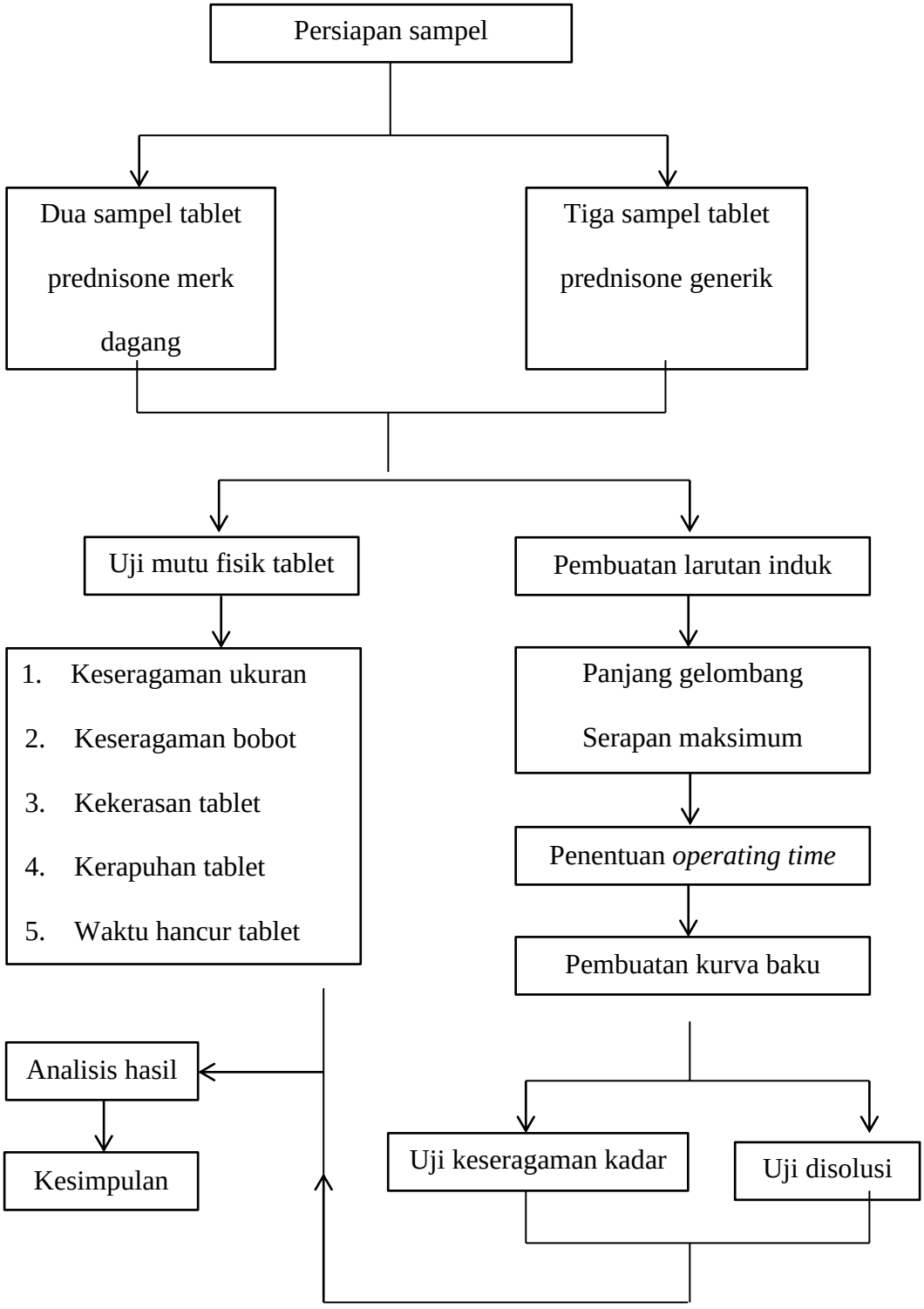
**Lampiran 1. Skema jalannya penelitian**



**Lampiran 2. Hasil pemeriksaan keseragaman ukuran tablet**

| Produk obat | Diameter tablet | Tebal tablet | Persyaratan | |
|---|---|---|---|---|
| | | | ≤1 1/3 xtebal | ≥ 3 x tebal |
| Obat ODA | 8.20 | 2.45 | 3.27 | 7.35 |
| | 8.20 | 2.45 | 3.27 | 7.35 |
| | 8.20 | 2.45 | 3.27 | 7.35 |
| | 8.20 | 2.40 | 3.20 | 7.2 |
| | 8.20 | 2.45 | 3.27 | 7.35 |
| Obat ODB | 6.10 | 3.00 | 4.00 | 9 |
| | 6.10 | 2.80 | 3.73 | 8.4 |
| | 6.10 | 3.00 | 4.00 | 9 |
| | 6.10 | 2.80 | 3.73 | 8.4 |
| | 6.10 | 2.75 | 3.67 | 8.25 |
| Obat OGC | 8.20 | 3.10 | 4.13 | 9.3 |
| | 8.15 | 3.00 | 4.00 | 9 |
| | 8.20 | 3.10 | 4.13 | 9.3 |
| | 8.20 | 3.10 | 4.13 | 9.3 |
| | 8.20 | 3.10 | 4.13 | 9.3 |
| Obat OGD | 8.20 | 3.35 | 4.47 | 10.05 |
| | 8.20 | 3.50 | 4.67 | 10.5 |
| | 8.20 | 3.40 | 4.53 | 10.2 |
| | 8.25 | 3.45 | 4.60 | 10.35 |
| | 8.15 | 3.40 | 4.53 | 10.2 |
| Obat OGE | 7.15 | 3.15 | 4.20 | 9.45 |
| | 7.20 | 3.05 | 4.07 | 9.15 |
| | 7.25 | 3.15 | 4.20 | 9.45 |
| | 7.15 | 3.15 | 4.20 | 9.45 |
| | 7.15 | 3.25 | 4.33 | 9.75 |

**Keterangan :**
**ObatODA :Obat bermerk dagang A**
**ObatODB :Obat bermerk dagang B**
**ObatOGC :Obat generik C**
**ObatOGD :Obat generik D**
**ObatOGE :Obat generik E**

**Lampiran 3. Hasil pemeriksaan keseragaman bobot dan perhitungan menurut persyaratan FI III**

**Obat ODA**

| No | Bobot | Penyimpangan x | Penyimpangan % |
|---|---|---|---|
| 1 | 151.8 | 0.0001 | 0.01 |
| 2 | 147.0 | 0.0315 | 3.15 |
| 3 | 153.5 | 0.0113 | 1.13 |
| 4 | 151.9 | 0.0008 | 0.08 |
| 5 | 151.9 | 0.0008 | 0.08 |
| 6 | 150.5 | 0.0084 | 0.84 |
| 7 | 149.9 | 0.0124 | 1.24 |
| 8 | 150.2 | 0.0104 | 1.04 |
| 9 | 152.1 | 0.0021 | 0.21 |
| 10 | 150.1 | 0.0111 | 1.11 |
| 11 | 156.0 | 0.0278 | 2.78 |
| 12 | 150.6 | 0.0078 | 0.78 |
| 13 | 151.5 | 0.0018 | 0.18 |
| 14 | 151.5 | 0.0018 | 0.18 |
| 15 | 150.9 | 0.0058 | 0.58 |
| 16 | 154.5 | 0.0179 | 1.79 |
| 17 | 148.9 | 0.0190 | 1.90 |
| 18 | 157.6 | 0.0383 | 3.83 |
| 19 | 154.2 | 0.0159 | 1.59 |
| 20 | 151.0 | 0.0051 | 0.51 |
| X | 151.78 | | |
| SD | 2.4343 | | |
| CV | 0.0160 | | |
| % CV | 1.6038 | | |

**Keterangan :**
**ObatODA :Obat bermerk dagang A**
**ObatODB :Obat bermerk dagang B**
**ObatOGC :Obat generik C**
**ObatOGD :Obat generik D**
**ObatOGE :Obat generik E**

**Obat ODB**

| No | Bobot | Penyimpangan x | Penyimpangan % |
|---|---|---|---|
| 1 | 99.8 | 0.0135 | 1.35 |
| 2 | 102.3 | 0.0111 | 1.11 |
| 3 | 101.5 | 0.0032 | 0.32 |
| 4 | 101.4 | 0.0023 | 0.23 |
| 5 | 99.9 | 0.0125 | 1.25 |
| 6 | 101.7 | 0.0052 | 0.52 |
| 7 | 101.5 | 0.0032 | 0.32 |
| 8 | 102.2 | 0.0101 | 1.01 |
| 9 | 102.3 | 0.0111 | 1.11 |
| 10 | 101.8 | 0.0062 | 0.62 |
| 11 | 100.3 | 0.0086 | 0.86 |
| 12 | 101.6 | 0.0042 | 0.42 |
| 13 | 98.9 | 0.0223 | 2.23 |
| 14 | 104.1 | 0.0288 | 2.88 |
| 15 | 104.2 | 0.0298 | 2.98 |
| 16 | 98.8 | 0.0233 | 2.33 |
| 17 | 100.6 | 0.0056 | 0.56 |
| 18 | 103.1 | 0.0190 | 1.90 |
| 19 | 100.9 | 0.0027 | 0.27 |
| 20 | 107.2 | 0.0593 | 5.93 |
| x | 101.71 | 0.0053 | 0.53 |
| SD | 1.9506 | | |
| CV | 0.0192 | | |
| % CV | 1.9179 | | |

**Obat OGC**

| No | Bobot | Penyimpangan x | Penyimpangan % |
|---|---|---|---|
| 1 | 153.7 | 0.0040 | 0.40 |
| 2 | 154.3 | 0.0001 | 0.01 |
| 3 | 151.5 | 0.0183 | 1.83 |
| 4 | 154.0 | 0.0021 | 0.21 |
| 5 | 155.2 | 0.0057 | 0.57 |
| 6 | 156.5 | 0.0141 | 1.41 |
| 7 | 157.5 | 0.0206 | 2.06 |
| 8 | 146.0 | 0.0539 | 5.39 |
| 9 | 150.0 | 0.0280 | 2.80 |
| 10 | 152.5 | 0.0118 | 1.18 |
| 11 | 156.4 | 0.0135 | 1.35 |
| 12 | 155.7 | 0.0089 | 0.89 |
| 13 | 155.8 | 0.0096 | 0.96 |
| 14 | 156.8 | 0.0161 | 1.61 |
| 15 | 159.8 | 0.0355 | 3.55 |
| 16 | 154.2 | 0.0008 | 0.08 |
| 17 | 157.0 | 0.0174 | 1.74 |
| 18 | 150.2 | 0.0267 | 2.67 |
| 19 | 149.6 | 0.0306 | 3.06 |
| 20 | 159.7 | 0.0349 | 3.49 |
| x | 154.32 | | |
| SD | 3.5189 | | |
| CV | 0.0228 | | |
| % CV | 2.2803 | | |

**Obat OGD**

| No | Bobot | Penyimpangan x | Penyimpangan % |
|---|---|---|---|
| 1 | 196.8 | 0.0060 | 0.60 |
| 2 | 195.3 | 0.0016 | 0.16 |
| 3 | 192.1 | 0.0180 | 1.80 |
| 4 | 195.3 | 0.0016 | 0.16 |
| 5 | 197.3 | 0.0086 | 0.86 |
| 6 | 195.5 | 0.0006 | 0.06 |
| 7 | 196.2 | 0.0030 | 0.30 |
| 8 | 194.2 | 0.0073 | 0.73 |
| 9 | 197.0 | 0.0071 | 0.71 |
| 10 | 199.8 | 0.0214 | 2.14 |
| 11 | 195.5 | 0.0006 | 0.06 |
| 12 | 197.4 | 0.0091 | 0.91 |
| 13 | 193.8 | 0.0093 | 0.93 |
| 14 | 198.0 | 0.0122 | 1.22 |
| 15 | 198.8 | 0.0163 | 1.63 |
| 16 | 191.0 | 0.0236 | 2.36 |
| 17 | 195.3 | 0.0016 | 0.16 |
| 18 | 198.7 | 0.0157 | 1.57 |
| 19 | 196.2 | 0.0030 | 0.30 |
| 20 | 188.2 | 0.0379 | 3.79 |
| x | 195.62 | | |
| SD | 2.7829 | | |
| CV | 0.0142 | | |
| % CV | 1.4226 | | |

**Obat OGE**

| No | Bobot | Penyimpangan x | Penyimpangan % |
|---|---|---|---|
| 1 | 157.8 | 0.0199 | 1.99 |
| 2 | 163.7 | 0.0580 | 5.80 |
| 3 | 150.8 | 0.0253 | 2.53 |
| 4 | 150.9 | 0.0247 | 2.47 |
| 5 | 157.6 | 0.0186 | 1.86 |
| 6 | 163.6 | 0.0574 | 5.74 |
| 7 | 153.2 | 0.0098 | 0.98 |
| 8 | 149.4 | 0.0344 | 3.44 |
| 9 | 149.0 | 0.0370 | 3.70 |
| 10 | 156.6 | 0.0122 | 1.22 |
| 11 | 151.9 | 0.0182 | 1.82 |
| 12 | 157.3 | 0.0167 | 1.67 |
| 13 | 157.6 | 0.0186 | 1.86 |
| 14 | 161.3 | 0.0425 | 4.25 |
| 15 | 152.0 | 0.0176 | 1.76 |
| 16 | 150.8 | 0.0253 | 2.53 |
| 17 | 151.7 | 0.0195 | 1.95 |
| 18 | 152.2 | 0.0163 | 1.63 |
| 19 | 157.0 | 0.0147 | 1.47 |
| 20 | 150.0 | 0.0305 | 3.05 |
| x | 154.72 | | |
| SD | 4.6227 | | |
| CV | 0.0299 | | |
| % CV | 2.9878 | | |

## Lampiran 4. Hasil pemeriksaan kekerasan tablet

| No | Kekerasan tablet (kg) | | | | |
|---|---|---|---|---|---|
| | Obat ODA | Obat ODB | Obat OGC | Obat OGD | Obat OGE |
| 1 | 7 | 7.1 | 7.1 | 7.3 | 9.6 |
| 2 | 8.6 | 7 | 6 | 9 | 9.2 |
| 3 | 7.4 | 8.7 | 6.9 | 9.4 | 9.2 |
| 4 | 7.5 | 8.2 | 7.6 | 8.9 | 8.3 |
| 5 | 8 | 11 | 6 | 6.8 | 8.2 |
| 6 | 7.5 | 9.8 | 7.8 | 8.4 | 8.5 |
| 7 | 7.2 | 10.1 | 6 | 8.6 | 8.5 |
| 8 | 8 | 8.8 | 6.4 | 7.4 | 8.5 |
| 9 | 7.4 | 6 | 6 | 6.8 | 9.1 |
| 10 | 7.7 | 10.1 | 7.4 | 7.8 | 9.2 |
| x | 7.63 | 8.68 | 6.72 | 8.04 | 8.83 |
| SD | 0.4644 | 1.6130 | 0.7269 | 0.9454 | 0.4809 |

### NPar Tests

**One-Sample Kolmogorov-Smirnov Test**

| | | ODA | ODB | OGC | OGD | OGE |
|---|---|---|---|---|---|---|
| N | | 10 | 10 | 10 | 10 | 10 |
| Normal Parameters[a,,b] | Mean | 7.630 | 8.680 | 6.720 | 8.040 | 8.830 |
| | Std. Deviation | .4644 | 1.6130 | .7269 | .9454 | .4809 |
| Most Extreme Differences | Absolute | .210 | .156 | .239 | .151 | .254 |
| | Positive | .210 | .136 | .239 | .151 | .254 |
| | Negative | -.110 | -.156 | -.161 | -.148 | -.213 |
| Kolmogorov-Smirnov Z | | .665 | .494 | .756 | .477 | .802 |
| Asymp. Sig. (2-tailed) | | .769 | .968 | .617 | .977 | .540 |

a. Test distribution is Normal.

b. Calculated from data.

### Oneway

**Test of Homogeneity of Variances**

Kekerasan tablet prednison

| Levene Statistic | df1 | df2 | Sig. |
|---|---|---|---|
| 6.305 | 4 | 45 | .000 |

**ANOVA**

Kekerasan tablet prednison

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Between Groups | 29.262 | 4 | 7.315 | 8.181 | .000 |
| Within Groups | 40.238 | 45 | .894 | | |
| Total | 69.500 | 49 | | | |

**Multiple Comparisons**

Kekerasan tablet prednison

LSD

| (I) Produk | (J) Produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | -1.0500* | .4229 | .017 | -1.902 | -.198 |
| | ODC | .9100* | .4229 | .037 | .058 | 1.762 |
| | OGD | -.4100 | .4229 | .337 | -1.262 | .442 |
| | OGE | -1.2000* | .4229 | .007 | -2.052 | -.348 |
| ODB | ODA | 1.0500* | .4229 | .017 | .198 | 1.902 |
| | ODC | 1.9600* | .4229 | .000 | 1.108 | 2.812 |
| | OGD | .6400 | .4229 | .137 | -.212 | 1.492 |
| | OGE | -.1500 | .4229 | .724 | -1.002 | .702 |
| ODC | ODA | -.9100* | .4229 | .037 | -1.762 | -.058 |
| | ODB | -1.9600* | .4229 | .000 | -2.812 | -1.108 |
| | OGD | -1.3200* | .4229 | .003 | -2.172 | -.468 |
| | OGE | -2.1100* | .4229 | .000 | -2.962 | -1.258 |
| OGD | ODA | .4100 | .4229 | .337 | -.442 | 1.262 |
| | ODB | -.6400 | .4229 | .137 | -1.492 | .212 |
| | ODC | 1.3200* | .4229 | .003 | .468 | 2.172 |
| | OGE | -.7900 | .4229 | .068 | -1.642 | .062 |
| OGE | ODA | 1.2000* | .4229 | .007 | .348 | 2.052 |
| | ODB | .1500 | .4229 | .724 | -.702 | 1.002 |
| | ODC | 2.1100* | .4229 | .000 | 1.258 | 2.962 |
| | OGD | .7900 | .4229 | .068 | -.062 | 1.642 |

**Multiple Comparisons**

Kekerasan tablet prednison

LSD

| (I) Produk | (J) Produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | -1.0500* | .4229 | .017 | -1.902 | -.198 |
| | ODC | .9100* | .4229 | .037 | .058 | 1.762 |
| | OGD | -.4100 | .4229 | .337 | -1.262 | .442 |
| | OGE | -1.2000* | .4229 | .007 | -2.052 | -.348 |
| ODB | ODA | 1.0500* | .4229 | .017 | .198 | 1.902 |
| | ODC | 1.9600* | .4229 | .000 | 1.108 | 2.812 |
| | OGD | .6400 | .4229 | .137 | -.212 | 1.492 |
| | OGE | -.1500 | .4229 | .724 | -1.002 | .702 |
| ODC | ODA | -.9100* | .4229 | .037 | -1.762 | -.058 |
| | ODB | -1.9600* | .4229 | .000 | -2.812 | -1.108 |
| | OGD | -1.3200* | .4229 | .003 | -2.172 | -.468 |
| | OGE | -2.1100* | .4229 | .000 | -2.962 | -1.258 |
| OGD | ODA | .4100 | .4229 | .337 | -.442 | 1.262 |
| | ODB | -.6400 | .4229 | .137 | -1.492 | .212 |
| | ODC | 1.3200* | .4229 | .003 | .468 | 2.172 |
| | OGE | -.7900 | .4229 | .068 | -1.642 | .062 |
| OGE | ODA | 1.2000* | .4229 | .007 | .348 | 2.052 |
| | ODB | .1500 | .4229 | .724 | -.702 | 1.002 |
| | ODC | 2.1100* | .4229 | .000 | 1.258 | 2.962 |
| | OGD | .7900 | .4229 | .068 | -.062 | 1.642 |

*. The mean difference is significant at the 0.05 level.

## Lampiran 5. Hasil pemeriksaan kerapuhan tablet

1. Produk bermerk dagang A (ODA)

| Bobot tablet | Replikasi | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Sebelum (gram) | 3.011 | 3.017 | 3.008 |
| Sesudah (gram) | 3.004 | 3.012 | 3.001 |
| Kerapuhan (%) | 0.2325 | 0.1657 | 0.2327 |
| x ± CV | | | 0,21 ± 0.04 |

2. Produk bermerk dagang B (ODB)

| Bobot tablet | Replikasi | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Sebelum (gram) | 2.036 | 2.031 | 2.028 |
| Sesudah (gram) | 2.033 | 2.027 | 2.024 |
| Kerapuhan (%) | 0.1473 | 0.1969 | 0.1972 |
| x ± CV | | | 0.18 ± 0.03 |

3. Produk generik (OGC)

| Bobot tablet | Replikasi | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Sebelum (gram) | 3.095 | 3.087 | 3.099 |
| Sesudah (gram) | 3.095 | 3.083 | 3.094 |
| Kerapuhan (%) | 0 | 0.1296 | 0.1613 |
| x ± CV | | | 0.10 ± 0.09 |

4. Produk generik (OGD)

| Bobot tablet | Replikasi | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Sebelum (gram) | 3.909 | 3.913 | 3.911 |
| Sesudah (gram) | 3.862 | 3.892 | 3.903 |
| Kerapuhan (%) | 1.2024 | 0.5367 | 0.2046 |
| x ± CV | | | 0.65 ± 0.51 |

5. Produk generik E (OGE)

| Bobot tablet | Replikasi | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Sebelum (gram) | 3.055 | 3.051 | 3.058 |
| Sesudah (gram) | 3.050 | 3.044 | 3.049 |
| Kerapuhan (%) | 0.1637 | 0.2294 | 0.2943 |
| x ± CV | | | 0.23 ± 0.07 |

Cara perhitungan kerapuhan tablet :

Produk bermerk dagang A (ODA)

$$\% \text{ Kerapuhan} = \frac{(\text{bobot sebelum uji} - \text{bobot sesudah uji})}{\text{bobot sebelum uji}} \times 100\ \%$$

$$= \frac{3.011\ \text{gr} - 3.004\ \text{gr}}{3.011\ \text{gr}} \times 100\ \%$$

$$= 0.2325\ \%$$

**NPar Tests**

**One-Sample Kolmogorov-Smirnov Test**

| | | ODA | ODB | OGC | OGD | OGE |
|---|---|---|---|---|---|---|
| N | | 3 | 3 | 3 | 3 | 3 |
| Normal Parameters[a,,b] | Mean | .21030 | .18047 | .09697 | .64790 | .22913 |
| | Std. Deviation | .038625 | .028724 | .085458 | .508110 | .065300 |
| Most Extreme Differences | Absolute | .384 | .383 | .315 | .253 | .175 |
| | Positive | .281 | .280 | .226 | .253 | .175 |
| | Negative | -.384 | -.383 | -.315 | -.196 | -.174 |
| Kolmogorov-Smirnov Z | | .665 | .663 | .546 | .439 | .303 |
| Asymp. Sig. (2-tailed) | | .768 | .771 | .927 | .991 | 1.000 |

a. Test distribution is Normal.

**Test of Homogeneity of Variances**

Kerapuhan tablet prednison

| Levene Statistic | df1 | df2 | Sig. |
|---|---|---|---|
| 5.902 | 4 | 10 | .061 |

**ANOVA**

Kerapuhan tablet prednison

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Between Groups | .558 | 4 | .139 | 2.563 | .104 |
| Within Groups | .544 | 10 | .054 | | |
| Total | 1.102 | 14 | | | |

**Multiple Comparisons**

Kerapuhan tablet prednisone

LSD

| (I) Produk | (J) Produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | .0298333 | .1904589 | .879 | -.394536 | .454202 |
| | ODC | .1133333 | .1904589 | .565 | -.311036 | .537702 |
| | OGD | -.4376000* | .1904589 | .044 | -.861969 | -.013231 |
| | OGE | -.0188333 | .1904589 | .923 | -.443202 | .405536 |
| ODB | ODA | -.0298333 | .1904589 | .879 | -.454202 | .394536 |
| | ODC | .0835000 | .1904589 | .670 | -.340869 | .507869 |
| | OGD | -.4674333* | .1904589 | .034 | -.891802 | -.043064 |
| | OGE | -.0486667 | .1904589 | .803 | -.473036 | .375702 |
| ODC | ODA | -.1133333 | .1904589 | .565 | -.537702 | .311036 |
| | ODB | -.0835000 | .1904589 | .670 | -.507869 | .340869 |
| | OGD | -.5509333* | .1904589 | .016 | -.975302 | -.126564 |
| | OGE | -.1321667 | .1904589 | .504 | -.556536 | .292202 |
| OGD | ODA | .4376000* | .1904589 | .044 | .013231 | .861969 |
| | ODB | .4674333* | .1904589 | .034 | .043064 | .891802 |
| | ODC | .5509333* | .1904589 | .016 | .126564 | .975302 |
| | OGE | .4187667 | .1904589 | .053 | -.005602 | .843136 |
| OGE | ODA | .0188333 | .1904589 | .923 | -.405536 | .443202 |
| | ODB | .0486667 | .1904589 | .803 | -.375702 | .473036 |
| | ODC | .1321667 | .1904589 | .504 | -.292202 | .556536 |
| | OGD | -.4187667 | .1904589 | .053 | -.843136 | .005602 |

*. The mean difference is significant at the 0.05 level.

## Lampiran 6. Hasil pemeriksaan waktu hancur

| No | Waktu Hancur | | | | |
|---|---|---|---|---|---|
| | ODA | ODB | OGC | OGD | OGE |
| 1 | 24 | 103 | 90 | 64 | 141 |
| 2 | 26 | 120 | 92 | 65 | 143 |
| 3 | 27 | 123 | 95 | 66 | 162 |
| 4 | 27 | 127 | 98 | 68 | 167 |
| 5 | 27 | 130 | 101 | 73 | 171 |
| 6 | 28 | 133 | 103 | 76 | 174 |
| x | 26.5 | 122.6667 | 96.5 | 68.66667 | 159.6667 |
| SD | 1.378405 | 10.70825 | 5.089204 | 4.802777 | 14.27819 |
| CV | 0.052015 | 0.087296 | 0.052738 | 0.069943 | 0.089425 |

**NPar Test**

**One-Sample Kolmogorov-Smirnov Test**

| | | ODA | ODB | OGC | OGD | OGE |
|---|---|---|---|---|---|---|
| N | | 6 | 6 | 6 | 6 | 6 |
| Normal Parameters[a,,b] | Mean | 26.5000 | 122.6667 | 96.5000 | 68.6667 | 159.6667 |
| | Std. Deviation | 1.37840 | 10.70825 | 5.08920 | 4.80278 | 14.27819 |
| Most Extreme Differences | Absolute | .308 | .235 | .145 | .222 | .232 |
| | Positive | .192 | .167 | .145 | .222 | .212 |
| | Negative | -.308 | -.235 | -.145 | -.166 | -.232 |
| Kolmogorov-Smirnov Z | | .755 | .576 | .355 | .543 | .567 |
| Asymp. Sig. (2-tailed) | | .619 | .895 | 1.000 | .929 | .904 |

a. Test distribution is Normal.

b. Calculated from data.

## Oneway

**Test of Homogeneity of Variances**

Waktuhancur tablet prednison (detik)

| Levene Statistic | df1 | df2 | Sig. |
|---|---|---|---|
| 5.275 | 4 | 25 | .003 |

**ANOVA**

Waktu hancur tablet prednison (detik)

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Between Groups | 62009.800 | 4 | 15502.450 | 209.833 | .000 |
| Within Groups | 1847.000 | 25 | 73.880 | | |
| Total | 63856.800 | 29 | | | |

**Multiple Comparisons**

Waktu hancur tablet prednison (detik)

LSD

| (I) Produk | (J) Produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | -96.1666667* | 4.9625262 | .000 | -106.387181 | -85.946153 |
| | ODC | -70.0000000* | 4.9625262 | .000 | -80.220514 | -59.779486 |
| | OGD | -42.1666667* | 4.9625262 | .000 | -52.387181 | -31.946153 |
| | OGE | -1.3316667E2 | 4.9625262 | .000 | -143.387181 | -122.946153 |
| ODB | ODA | 96.1666667* | 4.9625262 | .000 | 85.946153 | 106.387181 |
| | ODC | 26.1666667* | 4.9625262 | .000 | 15.946153 | 36.387181 |
| | OGD | 54.0000000* | 4.9625262 | .000 | 43.779486 | 64.220514 |
| | OGE | -37.0000000* | 4.9625262 | .000 | -47.220514 | -26.779486 |
| ODC | ODA | 70.0000000* | 4.9625262 | .000 | 59.779486 | 80.220514 |
| | ODB | -26.1666667* | 4.9625262 | .000 | -36.387181 | -15.946153 |
| | OGD | 27.8333333* | 4.9625262 | .000 | 17.612819 | 38.053847 |
| | OGE | -63.1666667* | 4.9625262 | .000 | -73.387181 | -52.946153 |
| OGD | ODA | 42.1666667* | 4.9625262 | .000 | 31.946153 | 52.387181 |
| | ODB | -54.0000000* | 4.9625262 | .000 | -64.220514 | -43.779486 |
| | ODC | -27.8333333* | 4.9625262 | .000 | -38.053847 | -17.612819 |
| | OGE | -91.0000000* | 4.9625262 | .000 | -101.220514 | -80.779486 |
| OGE | ODA | 133.1666667* | 4.9625262 | .000 | 122.946153 | 143.387181 |
| | ODB | 37.0000000* | 4.9625262 | .000 | 26.779486 | 47.220514 |
| | ODC | 63.1666667* | 4.9625262 | .000 | 52.946153 | 73.387181 |
| | OGD | 91.0000000* | 4.9625262 | .000 | 80.779486 | 101.220514 |

*. The mean difference is significant at the 0.05 level.

**Lampiran 7. Penentuan kurva baku prednison**

**a. Cara pembuatan seri konsentrasi kurva baku prednison**

Prednison $A_{1\ cm}^{1\%}$ = 415 a

Range 0,2 – 0,8

1. Untuk range 0,2

   A = a x b x c

   0,2 = 415 x 1 x c

   c = 4,8193 x $10^{-4}$ g/100 ml

   = 4,8 mg/L

2. Untuk range 0,8

   A = a x b x c

   0,2 = 415 x 1 x c

   c = 0,019277 x $10^{-3}$ g/100 ml

   = 19,277 mg/L

Pembuatan larutan baku 50 ppm sebanyak 500 ml aquadest

Penimbangan prednison = 25 mg

Perhitungan pembuatan seri larutan baku

1. Konsentrasi 5 mg/L sebanyak 50 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 50 ppm = 50 ml . 5 ppm

   $V_1$ = 5 ml ad 50 ml

2. Konsentrasi 6 mg/L sebanyak 50 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 50 ppm = 50 ml . 6 ppm

   $V_1$ = 6 ml ad 50 ml

3. Konsentrasi 7 mg/L sebanyak 50 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 50 ppm = 50 ml . 7 ppm

   $V_1$ = 7 ml ad 25 ml

4. Konsentrasi 8 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 8 ppm

$V_1$ = 8 ml ad 25 ml

5. Konsentrasi 9 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 9 ppm

$V_1$ = 9 ml ad 25 ml

6. Konsentrasi 10 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 10 ppm

$V_1$ = 10 ml ad 25 ml

7. Konsentrasi 12 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 12 ppm

$V_1$ = 12 ml ad 25 ml

8. Konsentrasi 14 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 14 ppm

$V_1$ = 14 ml ad 25 ml

9. Konsentrasi 16 mg/L sebanyak 50 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 50 ppm = 50 ml . 16 ppm

$V_1$ = 16 ml ad 25 ml

Pembuatan larutan baku 250 ppm sebanyak 100 ml etanol

Penimbangan prednison = 25 mg

Perhitungan pembuatan seri kurva baku

1. Konsentrasi 5 mg/L sebanyak 25 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 250 ppm = 25 ml . 5 ppm

   $V_1$ = 0.5 ml ad 25 ml

2. Konsentrasi 6 mg/L sebanyak 25 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 250 ppm = 25 ml . 6 ppm

   $V_1$ = 0.6 ml ad 25 ml

3. Konsentrasi 7 mg/L sebanyak 25 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 250 ppm = 25 ml . 7 ppm

   $V_1$ = 0.7 ml ad 25 ml

4. Konsentrasi 8 mg/L sebanyak 25 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 250 ppm = 25 ml . 8 ppm

   $V_1$ = 0.8 ml ad 25 ml

5. Konsentrasi 9 mg/L sebanyak 25 ml

   $V_1 . C_1$ = $V_2 . C_2$

   $V_1$ . 250 ppm = 25 ml . 9 ppm

$V_1$ = 0.9 ml ad 25 ml

6. Konsentrasi 10 mg/L sebanyak 25 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 250 ppm = 25 ml . 10 ppm

$V_1$ = 1 ml ad 25 ml

7. Konsentrasi 12 mg/L sebanyak 25 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 250 ppm = 25 ml . 12 ppm

$V_1$ = 1.2 ml ad 25 ml

8. Konsentrasi 14 mg/L sebanyak 25 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 250 ppm = 25 ml . 14 ppm

$V_1$ = 1.4 ml ad 25 ml

9. Konsentrasi 16 mg/L sebanyak 25 ml

$V_1 . C_1 = V_2 . C_2$

$V_1$ . 250 ppm = 25 ml . 16 ppm

$V_1$ = 1.6 ml ad 25 ml

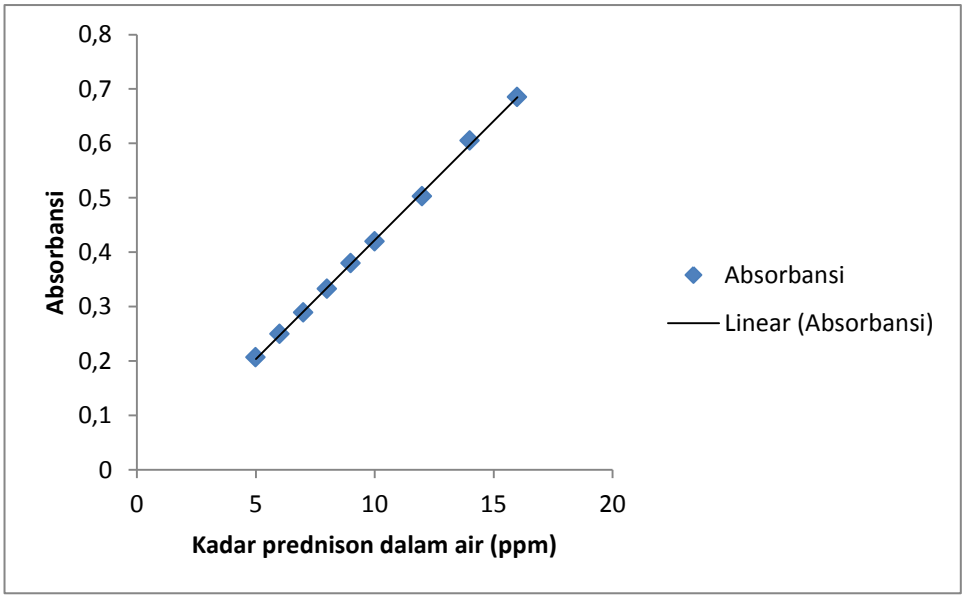
**b. Kurva baku prednisone dalam aquadest**

| Kadar prednison (ppm) | Absorbansi |
|---|---|
| 5 | 0.207 |
| 6 | 0.250 |
| 7 | 0.289 |
| 8 | 0.333 |
| 9 | 0.380 |
| 10 | 0.420 |
| 12 | 0.503 |
| 14 | 0.605 |
| 16 | 0.685 |

Regresi linier

a = - 0.015
b = 0.044
r = 0.999

Persamaan regresi linier Y =0.044X – 0.015



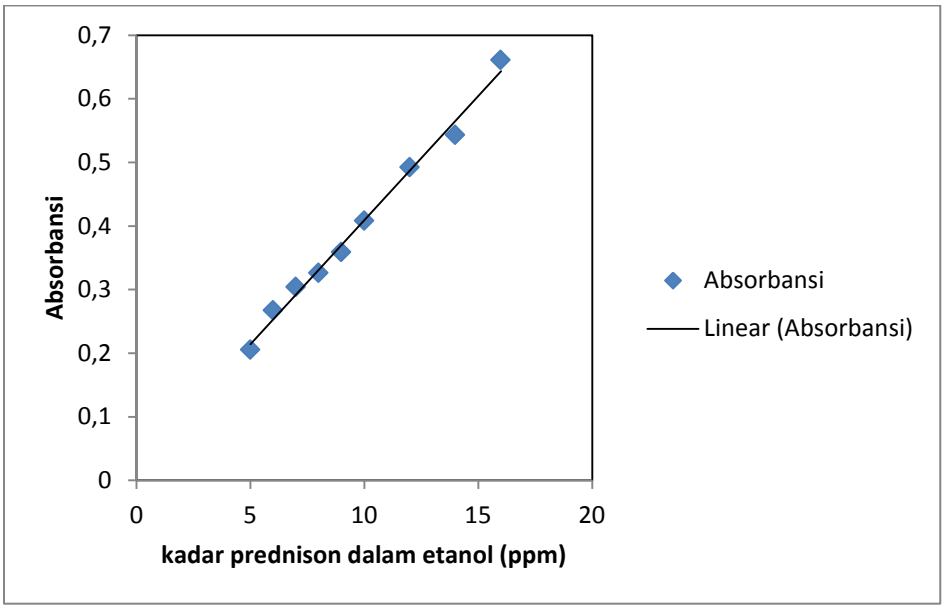
**Kurva baku prednisone dalam etanol**

| Kadar prednisone (ppm) | Absorbansi |
|---|---|
| 5 | 0.205 |
| 6 | 0.267 |
| 7 | 0.304 |
| 8 | 0.326 |
| 9 | 0.359 |
| 10 | 0.408 |
| 12 | 0.492 |
| 14 | 0.543 |
| 16 | 0.661 |

Regresi linier

a = 0.018
b = 0.039
r = 0.996

Persamaan regresi linier Y =0.039X + 0.018



**Lampiran 8. Hasil pemeriksaan keseragaman kadar**

| No | Kadar Prednison Dalam Tablet (mg) | | | | |
|---|---|---|---|---|---|
| | ODA | ODB | OGC | OGD | OGE |
| 1 | 5.02 | 5.08 | 5.10 | 5.32 | 4.94 |
| 2 | 5.15 | 4.96 | 4.93 | 5.18 | 5.35 |
| 3 | 5.10 | 5.49 | 5.36 | 5.17 | 5.05 |
| 4 | 5.39 | 5.73 | 5.29 | 5.36 | 4.84 |
| 5 | 4.93 | 5.15 | 4.89 | 5.13 | 5.23 |
| x | 5.14 | 5.28 | 5.11 | 5.23 | 5.08 |
| SD | 0.22 | 0.32 | 0.21 | 0.10 | 0.21 |
| CV(%) | 0.04 | 0.06 | 0.04 | 0.02 | 0.04 |

**Contoh perhitungan keseragaman tablet prednison**

Persamaan kurva baku Y = 0.039X + 0.018

Obat ODA (Obat dagang A)

| No | Bobot | | Absorbansi | Kadar | Kadar | Kadar /Tablet | % Kadar |
|---|---|---|---|---|---|---|---|
| | Tablet (mg) | Sampel (mg) | | mg/L | mg/ml | (mg) | tablet |
| 1 | 151.8 | 50 | 0.276 | 6.6154 | 0.0066 | 5.0211 | 100.4215 |
| 2 | 147.0 | 50 | 0.291 | 7.0000 | 0.0070 | 5.1450 | 102.9000 |
| 3 | 153.5 | 50 | 0.277 | 6.6410 | 0.0066 | 5.0970 | 101.9397 |
| 4 | 151.9 | 50 | 0.295 | 7.1026 | 0.0071 | 5.3944 | 107.8879 |
| 5 | 151.9 | 50 | 0.271 | 6.4872 | 0.0065 | 4.9270 | 98.5403 |

Y = 0.039X + 0.018

Konsentrasi = $\frac{\text{Absorbansi}-0.018}{0.039}$

$= \frac{0.276-0.018}{0.039}$

= 6.6154 mg/L
= 0.0066154 mg/ml

$$\text{Kadar per tablet} = \frac{\text{Konsentrasi x Bobot tablet x faktor pembuatan x faktor pengenceran}}{\text{Bobot sampel}}$$

$$= \frac{0.006615 \frac{\text{mg}}{\text{ml}} \text{ x } 151.8 \text{ mg x } 50 \text{ ml x } 5}{50 \text{ mg}}$$

$$= 5.0211 \text{ mg}$$

**Lampiran 9. Hasil pemeriksaan penetapan kadar**

| PRODUK | ABSORBANSI | KADAR mg/L | KADAR mg/ml | KADAR /TABLET | KADAR % |
|---|---|---|---|---|---|
| ODA | 0.411 | 10.07692 | 0.01008 | 5.038 | 100.769 |
| ODA | 0.443 | 10.89744 | 0.01090 | 5.449 | 108.974 |
| ODA | 0.432 | 10.61538 | 0.01062 | 5.308 | 106.154 |
| ODB | 0.419 | 10.28205 | 0.01028 | 5.141 | 102.821 |
| ODB | 0.420 | 10.30769 | 0.01031 | 5.154 | 103.077 |
| ODB | 0.435 | 10.69231 | 0.01069 | 5.346 | 106.923 |
| OGC | 0.426 | 10.46154 | 0.01046 | 5.231 | 104.615 |
| OGC | 0.405 | 9.92308 | 0.00992 | 4.962 | 99.231 |
| OGC | 0.409 | 10.02564 | 0.01003 | 5.013 | 100.256 |
| OGD | 0.408 | 10.00000 | 0.01000 | 5.000 | 100.000 |
| OGD | 0.400 | 9.79487 | 0.00979 | 4.897 | 97.949 |
| OGD | 0.417 | 10.23077 | 0.01023 | 5.115 | 102.308 |
| OGE | 0.413 | 10.12821 | 0.01013 | 5.064 | 101.282 |
| OGE | 0.432 | 10.61538 | 0.01062 | 5.308 | 106.154 |
| OGE | 0.429 | 10.53846 | 0.01054 | 5.269 | 105.385 |

**Contoh perhitungan penetapan kadar tablet prednison**

Persamaan kurva baku Y = 0.039X + 0.018

Obat ODA (Obat dagang A)

Y = 0.039X + 0.018

Konsentrasi = $\frac{\text{Absorbansi}-0.018}{0.039}$

= $\frac{0.411-0.018}{0.039}$

= 10.07962 mg/L
= 0.01008 mg/ml

Penetapan kadar = konsentrasi x faktor pengenceran x faktor pembuatan

= 0.01008 x 10 x 50
= 5.038

## Lampiran 10.Hasil pemeriksaan % kadar terdisolusi

### a. Produk bermerk dagang A (ODA)

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | | | x | SD |
|---|---|---|---|---|---|---|---|---|
| | Replikasi | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | |
| 2 | 98.4091 | 97.9545 | 97.2727 | 96.8182 | 97.0455 | 98.6364 | 97.689 | 0.75 |
| 5 | 101.8182 | 100.9091 | 100.0000 | 99.3182 | 100.2273 | 100.4545 | 100.455 | 0.85 |
| 10 | 104.0909 | 102.7273 | 103.1818 | 101.8182 | 102.2727 | 102.5000 | 102.765 | 0.79 |
| 15 | 106.8182 | 103.8636 | 103.6364 | 102.9545 | 103.8636 | 105.4545 | 104.432 | 1.43 |
| 20 | 107.7273 | 105.4545 | 104.0909 | 104.7727 | 104.5455 | 105.9091 | 105.417 | 1.30 |
| 25 | 108.1818 | 107.2727 | 105.9091 | 105.4545 | 106.3636 | 106.5909 | 106.629 | 0.98 |
| 30 | 107.9545 | 108.1818 | 107.5000 | 107.0455 | 108.1818 | 107.0455 | 107.652 | 0.53 |

### b. Produk bermerk dagang B (ODB)

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | | | x | SD |
|---|---|---|---|---|---|---|---|---|
| | Replikasi | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | |
| 2 | 61.1364 | 62.5000 | 63.8636 | 64.3182 | 65.9091 | 61.1364 | 63.144 | 1.90 |
| 5 | 92.7273 | 87.0455 | 84.7727 | 87.9546 | 84.7727 | 84.5455 | 86.970 | 3.15 |
| 10 | 96.8182 | 106.5909 | 105.2273 | 107.2727 | 107.5000 | 104.3182 | 104.621 | 4.01 |
| 15 | 102.5000 | 108.4091 | 105.9091 | 107.7273 | 109.0909 | 107.2727 | 106.818 | 2.37 |
| 20 | 106.3636 | 108.6364 | 106.3636 | 108.6364 | 107.7273 | 107.7273 | 107.576 | 1.02 |
| 25 | 107.2727 | 109.3182 | 107.2727 | 108.8636 | 108.1818 | 108.6364 | 108.258 | 0.85 |
| 30 | 109.3182 | 109.7727 | 109.3182 | 109.5455 | 109.7727 | 108.8636 | 109.432 | 0.34 |

### c. Produk generik C (OGC)

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | | | x | SD |
|---|---|---|---|---|---|---|---|---|
| | Replikasi | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | |
| 2 | 41.1364 | 57.2727 | 56.5909 | 55.4546 | 57.7273 | 58.4091 | 54.432 | 6.59 |
| 5 | 62.7273 | 77.7273 | 74.5455 | 75.2273 | 79.7727 | 80.2273 | 75.038 | 6.46 |
| 10 | 82.9545 | 84.7727 | 84.5455 | 82.7273 | 84.5455 | 85.0000 | 84.091 | 0.99 |
| 15 | 94.3182 | 94.5455 | 98.8636 | 96.8182 | 95.2273 | 99.0909 | 96.477 | 2.13 |
| 20 | 109.3182 | 102.9545 | 102.2727 | 103.1818 | 102.2727 | 103.1818 | 103.864 | 2.70 |
| 25 | 109.5455 | 108.6364 | 108.8636 | 108.1818 | 108.4091 | 107.5000 | 108.523 | 0.69 |
| 30 | 109.7727 | 109.0909 | 109.3182 | 108.6364 | 109.0909 | 108.1818 | 109.015 | 0.55 |

### d. Produk generik D (OGD)

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | | | x | SD |
|---|---|---|---|---|---|---|---|---|
| | Replikasi | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | |
| 2 | 50.2273 | 63.4091 | 64.5455 | 62.2727 | 61.1364 | 65.9091 | 61.250 | 5.65 |
| 5 | 87.0455 | 85.6818 | 87.0455 | 83.4091 | 86.3636 | 87.2727 | 86.136 | 1.46 |
| 10 | 90.0000 | 98.8636 | 100.2273 | 102.0455 | 99.0909 | 102.0455 | 98.712 | 4.49 |
| 15 | 103.1818 | 103.6364 | 102.5000 | 103.6364 | 102.5000 | 105.4545 | 103.485 | 1.09 |
| 20 | 105.4545 | 105.6818 | 103.6364 | 103.1818 | 104.5455 | 105.9091 | 104.735 | 1.14 |
| 25 | 105.9091 | 106.1364 | 104.7727 | 104.0909 | 105.4545 | 106.1364 | 105.417 | 0.83 |
| 30 | 106.5909 | 106.3636 | 105.9091 | 105.4545 | 107.2727 | 106.5909 | 106.364 | 0.63 |

### e. Produk generik E (OGE)

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | | | x | SD |
|---|---|---|---|---|---|---|---|---|
| | Replikasi | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | |
| 2 | 62.2727 | 40.9091 | 41.8182 | 41.3636 | 40.9091 | 43.8636 | 45.189 | 8.44 |
| 5 | 80.0000 | 92.0455 | 93.8636 | 93.1818 | 94.0909 | 92.9546 | 91.023 | 5.45 |
| 10 | 99.3182 | 95.4545 | 97.7273 | 98.1818 | 95.6818 | 98.4091 | 97.462 | 1.56 |
| 15 | 101.5909 | 97.9545 | 98.6364 | 98.4091 | 97.5000 | 99.0909 | 98.864 | 1.44 |
| 20 | 103.4091 | 99.7727 | 100.6818 | 99.3182 | 99.0909 | 100.4545 | 100.455 | 1.57 |
| 25 | 105.9091 | 101.8182 | 102.2727 | 103.1818 | 102.0455 | 103.1818 | 103.068 | 1.51 |
| 30 | 106.3636 | 106.8182 | 104.5455 | 105.9091 | 103.6364 | 104.7727 | 105.341 | 1.22 |

### Rata-rata kadar terdisolusi prednison

| Waktu (menit) | Kadar Obat Terdisolusi % | | | | |
|---|---|---|---|---|---|
| | Replikasi | | | | |
| | ODA | ODB | OGC | OGD | OGE |
| 2 | 97.689 | 63.144 | 54.432 | 61.25 | 45.189 |
| 5 | 100.455 | 86.97 | 75.038 | 86.136 | 91.023 |
| 10 | 102.765 | 104.621 | 84.091 | 98.712 | 97.462 |
| 15 | 104.432 | 106.818 | 96.477 | 103.485 | 98.864 |
| 20 | 105.417 | 107.576 | 103.864 | 104.735 | 100.455 |
| 25 | 106.629 | 108.258 | 108.523 | 105.417 | 103.068 |
| 30 | 107.652 | 109.432 | 109.015 | 106.364 | 105.341 |

**Contoh perhitungan kadar terdisolusi prednison**

Obat merk dagang A (ODA)

Persamaan kurva baku Y = 0.044 X – 0.015

| Waktu (menit) | Absorbansi | Kadar (ppm) | Kadar mg/ml | Kadar mg/500 ml | Fraksi Pengenceran | Kadar terdisolusi (%) |
|---|---|---|---|---|---|---|
| 2 | 0.418 | 9.84090909 | 0.00984091 | 4.92045455 | 4.920454545 | 98.40909091 |
| 5 | 0.433 | 10.1818182 | 0.01018182 | 5.09090909 | 5.090909091 | 101.8181818 |
| 10 | 0.443 | 10.4090909 | 0.01040909 | 5.20454545 | 5.204545455 | 104.0909091 |
| 15 | 0.455 | 10.6818182 | 0.01068182 | 5.34090909 | 5.340909091 | 106.8181818 |
| 20 | 0.459 | 10.7727273 | 0.01077273 | 5.38636364 | 5.386363636 | 107.7272727 |
| 25 | 0.461 | 10.8181818 | 0.01081818 | 5.40909091 | 5.409090909 | 108.1818182 |
| 30 | 0.46 | 10.7954545 | 0.01079545 | 5.39772727 | 5.397727273 | 107.9545455 |

1. Kadar ppm diperoleh dari memasukkan serapan (absorbansi) yang diperoleh pada kurva baku Y = 0.044 X – 0.015, dimana y adalah serapan pada menit ke– 2 adalah 0.418 sehingga diperoleh x = 9.84090909 ppm
2. Kadar mg/ml didapat dari hasil pembagian 9.84090909 : 1000 sehingga diperoleh 0.00984091 mg/ml
3. Kadar mg/500 ml (medium disolusi prednison), didapat dari 0.00984091 x 500 sehingga diperoleh 4.92045455 mg/500ml
4. Fraksi pengenceran diperoleh dari 4.92045455 x 1 sehingga diperoleh 4.92045455
5. Kadar terdisolusi dalam satuan persen diperoleh dari fraksi pengenceran dibagi dosis prednisone (5mg) dikali100% diperoleh hasil 98.40909091 %

## Lampiran 11. Hasil perhitungan Q30 (%)

| Replikasi | Q30(%) | | | | |
|---|---|---|---|---|---|
| | ODA | ODB | OGC | OGD | OGE |
| 1 | 107.955 | 109.318 | 109.773 | 106.591 | 106.364 |
| 2 | 108.182 | 109.773 | 109.091 | 106.364 | 106.818 |
| 3 | 107.500 | 109.318 | 109.318 | 105.909 | 104.546 |
| 4 | 107.046 | 109.546 | 108.636 | 105.455 | 105.909 |
| 5 | 108.182 | 109.773 | 109.091 | 107.273 | 103.636 |
| 6 | 107.046 | 108.864 | 108.182 | 106.591 | 104.773 |
| x | 107.652 | 109.432 | 109.015 | 106.364 | 105.341 |
| SD | 0.531 | 0.345 | 0.550 | 0.627 | 1.218 |

**One-Sample Kolmogorov-Smirnov Test**

| | | ODA | ODB | OGC | OGD | OGE |
|---|---|---|---|---|---|---|
| N | | 6 | 6 | 6 | 6 | 6 |
| Normal Parameters[a,,b] | Mean | 107.65183 | 109.43200 | 109.01517 | 106.36383 | 105.34100 |
| | Std. Deviation | .531260 | .344724 | .550537 | .626521 | 1.217568 |
| Most Extreme Differences | Absolute | .216 | .204 | .221 | .192 | .180 |
| | Positive | .206 | .161 | .124 | .192 | .180 |
| | Negative | -.216 | -.204 | -.221 | -.167 | -.180 |
| Kolmogorov-Smirnov Z | | .529 | .499 | .542 | .470 | .440 |
| Asymp. Sig. (2-tailed) | | .942 | .964 | .930 | .980 | .990 |

a. Test distribution is Normal.

b. Calculated from data.

**Test of Homogeneity of Variances**

Q30(%)

| Levene Statistic | df1 | df2 | Sig. |
|---|---|---|---|
| 4.648 | 4 | 25 | .006 |

**ANOVA**

Q30(%)

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Between Groups | 71.911 | 4 | 17.978 | 34.852 | .000 |
| Within Groups | 12.896 | 25 | .516 | | |
| Total | 84.806 | 29 | | | |

**Multiple Comparisons**

Q30(%)

LSD

| (I) produk | (J) produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | -1.780167* | .414662 | .000 | -2.63418 | -.92616 |
| | ODC | -1.363333* | .414662 | .003 | -2.21734 | -.50932 |
| | OGD | 1.288000* | .414662 | .005 | .43399 | 2.14201 |
| | OGE | 2.310833* | .414662 | .000 | 1.45682 | 3.16484 |
| ODB | ODA | 1.780167* | .414662 | .000 | .92616 | 2.63418 |
| | ODC | .416833 | .414662 | .324 | -.43718 | 1.27084 |
| | OGD | 3.068167* | .414662 | .000 | 2.21416 | 3.92218 |
| | OGE | 4.091000* | .414662 | .000 | 3.23699 | 4.94501 |
| ODC | ODA | 1.363333* | .414662 | .003 | .50932 | 2.21734 |
| | ODB | -.416833 | .414662 | .324 | -1.27084 | .43718 |
| | OGD | 2.651333* | .414662 | .000 | 1.79732 | 3.50534 |
| | OGE | 3.674167* | .414662 | .000 | 2.82016 | 4.52818 |
| OGD | ODA | -1.288000* | .414662 | .005 | -2.14201 | -.43399 |
| | ODB | -3.068167* | .414662 | .000 | -3.92218 | -2.21416 |
| | ODC | -2.651333* | .414662 | .000 | -3.50534 | -1.79732 |
| | OGE | 1.022833* | .414662 | .021 | .16882 | 1.87684 |
| OGE | ODA | -2.310833* | .414662 | .000 | -3.16484 | -1.45682 |
| | ODB | -4.091000* | .414662 | .000 | -4.94501 | -3.23699 |
| | ODC | -3.674167* | .414662 | .000 | -4.52818 | -2.82016 |
| | OGD | -1.022833* | .414662 | .021 | -1.87684 | -.16882 |

*. The mean difference is significant at the 0.05 level.

**Lampiran 12. Hasil perhitungan DE30%**

| Replikasi | DE30(%) | | | | |
|---|---|---|---|---|---|
| | ODA | ODB | OGC | OGD | OGE |
| 1 | 101.9091 | 95.39393 | 86.96213 | 92.09847 | 93.09091 |
| 2 | 100.5189 | 98.12122 | 89.37879 | 94.62501 | 90.41667 |
| 3 | 99.86743 | 96.5303 | 89.52272 | 94.33334 | 91.26515 |
| 4 | 99.39771 | 98.29925 | 88.85606 | 93.92425 | 91.21212 |
| 5 | 99.97348 | 98.02651 | 89.61363 | 94.14773 | 90.31062 |
| 6 | 100.6098 | 96.76516 | 90.375 | 95.93561 | 91.63635 |
| x | 100.3794 | 97.1894 | 89.11806 | 94.1774 | 91.32197 |
| SD | 0.87 | 1.15 | 1.16 | 1.24 | 1.01 |

**Contoh perhitungan DE30 (%)**

**Obat merk dagang A (ODA) Replikasi 1**

| Waktu (menit) | Kadar terdisolusi | Perhitungan | AUC |
|---|---|---|---|
| 2 | 98.40909 | 1/2 x 2 x 98.40909 | 98.40909 |
| 5 | 101.8182 | 1/2 x (5 - 2) x (98.40909 + 101.8182) | 300.3409 |
| 10 | 104.0909 | 1/2 x (10 - 5) x (104.0909 + 101.8182) | 514.7728 |
| 15 | 106.8182 | 1/2 x (15 -10) x (106.8182 + 104.0909) | 527.2728 |
| 20 | 107.7273 | 1/2 x (20 - 15) x (107.7273 + 106.8182) | 536.3638 |
| 25 | 108.1818 | 1/2 x (25 - 20) x (108.1818 + 107.7273) | 539.7728 |
| 30 | 107.9545 | 1/2 x (30 - 25) x (107.9545 + 108.1818) | 540.3408 |
| AUC 30 | | | 3057.2730 |

Harga DE30 (%) dihitung :

$$DE30(\%) = \frac{\text{AUC } 30}{30 \text{ x } 100} \text{ x } 100\%$$

$$= \frac{3057.2730}{3000} \text{ x } 100\%$$

$$= 101.9091$$

**One-Sample Kolmogorov-Smirnov Test**

| | | ODA | ODB | OGC | OGD | OGE |
|---|---|---|---|---|---|---|
| N | | 6 | 6 | 6 | 6 | 6 |
| Normal Parameters[a,,b] | Mean | 100.37940 | 97.18940 | 89.11805 | 94.17740 | 91.32197 |
| | Std. Deviation | .872138 | 1.152295 | 1.163950 | 1.241200 | 1.008531 |
| Most Extreme Differences | Absolute | .229 | .266 | .255 | .253 | .211 |
| | Positive | .229 | .168 | .168 | .193 | .211 |
| | Negative | -.130 | -.266 | -.255 | -.253 | -.158 |
| Kolmogorov-Smirnov Z | | .561 | .652 | .625 | .619 | .517 |
| Asymp. Sig. (2-tailed) | | .911 | .789 | .829 | .839 | .952 |

a. Test distribution is Normal.

b. Calculated from data.

**Test of Homogeneity of Variances**

DE30 (%)

| Levene Statistic | df1 | df2 | Sig. |
|---|---|---|---|
| .200 | 4 | 25 | .936 |

**ANOVA**

DE30 (%)

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Between Groups | 485.699 | 4 | 121.425 | 101.172 | .000 |
| Within Groups | 30.005 | 25 | 1.200 | | |
| Total | 515.703 | 29 | | | |

**Multiple Comparisons**

DE30 (%)

LSD

| (I) produk | (J) produk | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| ODA | ODB | 3.190008* | .632503 | .000 | 1.88734 | 4.49267 |
| | OGC | 11.261348* | .632503 | .000 | 9.95868 | 12.56401 |
| | OGD | 6.202002* | .632503 | .000 | 4.89934 | 7.50467 |
| | OGE | 9.057433* | .632503 | .000 | 7.75477 | 10.36010 |
| ODB | ODA | -3.190008* | .632503 | .000 | -4.49267 | -1.88734 |
| | OGC | 8.071340* | .632503 | .000 | 6.76868 | 9.37400 |
| | OGD | 3.011993* | .632503 | .000 | 1.70933 | 4.31466 |
| | OGE | 5.867425* | .632503 | .000 | 4.56476 | 7.17009 |
| OGC | ODA | -11.261348* | .632503 | .000 | -12.56401 | -9.95868 |
| | ODB | -8.071340* | .632503 | .000 | -9.37400 | -6.76868 |
| | OGD | -5.059347* | .632503 | .000 | -6.36201 | -3.75668 |
| | OGE | -2.203915* | .632503 | .002 | -3.50658 | -.90125 |
| OGD | ODA | -6.202002* | .632503 | .000 | -7.50467 | -4.89934 |
| | ODB | -3.011993* | .632503 | .000 | -4.31466 | -1.70933 |
| | OGC | 5.059347* | .632503 | .000 | 3.75668 | 6.36201 |
| | OGE | 2.855432* | .632503 | .000 | 1.55277 | 4.15810 |
| OGE | ODA | -9.057433* | .632503 | .000 | -10.36010 | -7.75477 |
| | ODB | -5.867425* | .632503 | .000 | -7.17009 | -4.56476 |
| | OGC | 2.203915* | .632503 | .002 | .90125 | 3.50658 |
| | OGD | -2.855432* | .632503 | .000 | -4.15810 | -1.55277 |

*. The mean difference is significant at the 0.05 level.

**Lampiran 13.Hasil perhitungan nilai F2**

Produk uji : 1. Obat ODA
2. Obat ODB
3. Obat OGC
4. Obat OGD
5. Obat OGE

| No | Produk Obat | similarity factor |
|---|---|---|
| | | F2 |
| 1 | ODA –ODB | 42.45989 |
| 2 | ODA-OGC | 34.40369 |
| 3 | ODA-OGD | 41.29408 |
| 4 | ODA-OGE | 34.36728 |
| 5 | ODB-OGC | 48.99736 |
| 6 | ODB-OGD | 73.16814 |
| 7 | ODB-OGE | 52.52602 |
| 8 | OGC-OGD | 54.62985 |
| 9 | OGC-OGE | 51.90603 |
| 10 | OGD-OGE | 57.94893 |

Contoh perhitungan nilai F2 :

Obat ODB (R)

Obat OGD (T)

| Waktu (menit) | R | T | R-T | \|A-B\|2 |
|---|---|---|---|---|
| 2 | 63.14394 | 61.2499989 | 1.8939411 | 3.587013 |
| 5 | 86.9697 | 86.1363638 | 0.8333362 | 0.694449 |
| 10 | 104.6212 | 98.7121411 | 5.9090589 | 34.91698 |
| 15 | 106.8182 | 103.484847 | 3.333353 | 11.11124 |
| 20 | 107.5758 | 104.734861 | 2.840939 | 8.070934 |
| 25 | 108.2576 | 105.416659 | 2.840941 | 8.070946 |
| 30 | 109.4318 | 106.363624 | 3.068176 | 9.413704 |
| | | | ∑(RT)2 | 75.86527 |

$$F_2 = 50 \log \left[ \frac{100}{\sqrt{1 + \frac{\sum_{t=1}^{t=n} (Rt - Tt)^2}{n}}} \right]$$

$$= 50 \log \left[ \frac{100}{\sqrt{1 + \frac{75.86527}{7}}} \right]$$

$$= 50 \log \left[ \frac{100}{\sqrt{1 + 10.8379}} \right]$$

$$= 50 \log \left[ \frac{100}{\sqrt{11.8379}} \right]$$

$$= 50 \log \left[ \frac{100}{3.440624} \right]$$

$$= 50 \log [29.06449]$$

$$= 50.\ 1.463363$$

$$= 73.16814$$

**Lampiran 15. Foto alat**

Neraca analitik


Disintegrator tester

Hardness tester


Friabilator tester

Dissolution tester tipe 2

Spektrofotometer UV - Vis