Chapter 833

Tolerance Intervals for Gamma Data

Introduction

This routine calculates the sample size needed to obtain a specified coverage of a β-content tolerance limit at a stated confidence level for data from the gamma distribution. These intervals are constructed so that they contain at least 100β% of the population with probability of at least 100(1 - α)%. For example, in water management, a drinking water standard might be that one is 95% confident that certain chemical concentrations are not exceeded more than 3% of the time.

Difference between a Confidence Interval and a Tolerance Interval

It is easy to get confused about the difference between a confidence interval and a tolerance interval. Just remember than a confidence interval is a probability statement about the value of a distributional parameter such as the mean or proportion. On the other hand, a tolerance interval is a probability statement about a proportion of the distribution from which the sample is drawn.

Technical Details

The gamma distribution finds many uses. The two-parameter gamma density function is

\[ f(x; R, \theta) = \frac{x^{R-1}}{\theta^R \Gamma(R)} \exp(-x/\theta), \quad x > 0, \theta > 0, R > 0. \]

The parameter \( R \) is referred to as the shape parameter and \( \theta \) as the scale parameter.

Following Guenther (1977), a tolerance limit is constructed from a random sample so that a specified proportion of the population is contained either above or below the limit. The limit is of the form

\[ L_1 = k \bar{x} \]

where \( \bar{x} \) is the sample mean and \( k \) is calculated as described below.

Proportion of the Population Covered

An important concept is that of coverage. Coverage is the proportion of the population distribution that is above or below the limit.
Solving for N

Let $N$ be the sample size, $P$ the proportion of the population covered, $(1 - \alpha)$ the confidence level, $\delta$ the proportion exceedance margin, and $\alpha'$ the probability that the coverage is greater than $P + \delta$. Guenther (1977) shows that the minimum value of $N$ for a **lower, one-sided tolerance limit** is the smallest value of $N$ that satisfies

$$\frac{\chi^2_{2RN;1-\alpha}}{\chi^2_{2RN;\alpha'}} \leq \frac{\chi^2_{2R;1-P}}{\chi^2_{2R;1-P-\delta}}$$

The value of $k$ is given by

$$k = \frac{NX^2_{2R;1-P}}{X^2_{2RN;1-\alpha}}.$$

Guenther (1977) also shows that the minimum value of $N$ for an **upper, one-sided tolerance limit** is the smallest value of $N$ that satisfies

$$\frac{\chi^2_{2RN;\alpha}}{\chi^2_{2RN;1-\alpha'}} \geq \frac{\chi^2_{2R;P}}{\chi^2_{2R;P+\delta}}$$

The value of $k$ is given by

$$k = \frac{NX^2_{2R;P}}{X^2_{2RN;\alpha}}.$$

where $\chi^2_{df;P}$ is the $p^{th}$ quantile of a chi-square distribution with $df$ degrees of freedom.

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**Procedure Options**

This section describes the options that are specific to this procedure. These are located on the Design tab. For more information about the options of other tabs, go to the Procedure Window chapter.

**Design Tab**

The Design tab contains most of the parameters and options that you will be concerned with.

**Solve For**

**Solve For**

Select the parameter you want to solve for: sample size ($N$) or exceedance margin ($\delta$). The parameter you select here will be shown on the vertical axis in the plots.

**Sample Size $N$**

A search is conducted for the minimum sample size that adheres to the parameter values. Remember that the search is based on two inequalities, so the particular values of the confidence level and alpha' may not be met exactly.

**Exceedance Margin $\delta$**

A search is conducted for the value of $\delta$ that meets the requirements of the confidence level and alpha' inequalities.

$$\alpha' = Pr(p \geq P + \delta)$$

$\alpha'$ is the probability that the sample coverage is $\geq P + \delta$. A search is conducted for the value of $\alpha'$ that meets the requirements of the other settings.
**Gamma Parameter**

**Shape Parameter**
Enter a value for the *shape* parameter of the gamma distribution. It is assumed that this value is known.

**Range**
This value can be any value > 0.

**Standard form of gamma distribution**

\[ f(x; R) = \frac{x^{R-1}}{\Gamma(R)} \exp(-x), \quad x > 0, \ R > 0 \]

where \( A \) is the shape parameter.

**Exponential distribution**
When \( R = 1 \), the gamma reduces to the exponential distribution.

**Erlang distribution**
When \( R \) is a positive integer, the gamma is called the Erlang distribution.

**Chi-square distribution**
When the scale parameter is 2, the gamma is the chi-square distribution with \( 2R \) degrees of freedom.

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**Upper or Lower Tolerance Limit**

**Limit Type**
Specify whether the tolerance limit (or bound) is an upper limit or a lower limit. In either case, this is a one-sided limit.

**Upper Tolerance Limit**
An upper tolerance bound will be used.

**Lower Tolerance Limit**
A lower tolerance bound will be used.

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**Sample Size**

**N (Sample Size)**
Enter one or more values for the sample size. This is the number of individuals selected at random from the population to be in the study.

You can enter a single value or a range of values.

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**Proportion of Population Covered**

**Proportion Covered (P)**
Enter the proportion of the population that is above or below the tolerance limit.

If a lower limit (L1) is specified, this is the desired area of the probability distribution above L1. If \( F(x) \) is the CDF of the distribution, \( P = 1 - F(L1) \).

If an upper limit (L2) is specified, this is the desired area of the probability distribution below L2. If \( F(x) \) is the CDF of the distribution, \( P = F(L2) \).
The possible range is $0 < P < 1 - \delta$. Usually, one of the values 0.80, 0.90, 0.95, or 0.99 is used.

You can enter a single value such as 0.9, a series of values such as 0.8 0.9 0.99, or a range such as 0.8 to 0.98 by 0.02.

**Confidence Level (1 - $\alpha$)**

Specify the proportion of tolerance limits (constructed with these parameter settings) that would have the same coverage. The absolute range is $0 < 1 - \alpha < 1$. The typical range is $0.8 < 1 - \alpha < 1$.

Usually, one of the values 0.90, 0.95, and 0.99 is used. You can enter a single value such as 0.95, a series of values such as 0.9 0.95 0.99, or a range such as 0.8 to 0.95 by 0.01.

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**Proportion Covered Exceedance**

**Proportion Covered Exceedance Margin ($\delta$)**

$\delta$ is added to $P$ to set an upper bound of $P' = P + \delta$ on the coverage. Hence, $\delta$ represents a precision value for $P$.

The value of $P'$ is set to occur with a low probability (0.05 or 0.01).

For example, if $P = 0.9$ and $\delta = 0.01$, then the parameters are set so that a coverage of 0.9 occurs with high probability, but a coverage of 0.91 occurs with low probability.

The possible range is $0 < \delta < 1 - P$. Usually 0.1, 0.05, or 0.01 is used.

You can enter a single value such as 0.02 or a series of values such as 0.01 0.02 0.05 or a range such as 0.01 to 0.05 by 0.01

$\alpha' = Pr(p \geq P + \delta)$

$\alpha'$ is the probability that the sample coverage $p$ is greater than $P + \delta$. It is set to a small value such as 0.05 or 0.01.

The range is $0.0 < \alpha' < 0.5$. Usually 0.1, 0.05, or 0.01 is used.

You can enter a single value such as 0.05, a series of values such as 0.01 0.02 0.05, or a range of values such as 0.01 to 0.05 by 0.01.
Example 1 – Calculating Sample Size

Suppose a study is planned to determine the sample size required to compute a lower 95% tolerance limit that covers 90% of a gamma population in which the shape parameter is 5. The researcher wants to investigate using a $\delta$ of 0.01, 0.02, or 0.05 with an $\alpha'$ of 0.05.

Setup

This section presents the values of each of the parameters needed to run this example. First load the Tolerance Intervals for Gamma Data procedure window. You may then make the appropriate entries as listed below, or open Example 1 by going to the File menu and choosing Open Example Template.

Option | Value
--- | ---
Design Tab | Solve For Sample Size
Shape Parameter | 5
Limit Type | Lower Tolerance Limit
Proportion Covered ($P$) | 0.9
Confidence Level ($1 - \alpha$) | 0.95
Coverage Proportion Exceedance ($\delta$) | 0.01 0.025 0.05
$\alpha' = Pr(p \geq P + \delta)$ | 0.05

Annotated Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

| Confidence Level 1 - $\alpha$ | Sample Size | Proportion Covered $P$ | Proportion Covered Exceedance Margin $\delta$ | $P + \delta$ | $Pr(p \geq P + \delta)$ | $\alpha'$ | Tolerance Factor $k$
|---|---|---|---|---|---|---|---
| 0.950 | 1929 | 0.9000 | 0.0100 | 0.9100 | 0.050 | 0.4785
| 0.950 | 267 | 0.9000 | 0.0250 | 0.9250 | 0.050 | 0.4654
| 0.950 | 49 | 0.9000 | 0.0500 | 0.9500 | 0.050 | 0.4394

References


Report Definitions

Confidence Level ($1 - \alpha$) is the proportion of studies with the same settings that produce tolerance intervals with a proportion covered of at least $P$.

$N$ is the number of subjects.

Proportion Covered $P$ is the proportion of the population covered. It is the probability of being greater than the tolerance limit based on the gamma distribution.

Proportion Covered Exceedance Margin $\delta$ is the value that is added to $P$ to set an upper bound on the coverage at $P + \delta$.

$P + \delta$ is the upper limit of the proportion covered $P$. It is a measure of the precision (closeness) of the actual coverage to $P$.

$\alpha' = Pr(p \geq P + \delta)$ is the probability that the coverage computed from a random sample ($p$) is greater than $P + \delta$. It is set to a small value such as 0.05 or 0.01.

$k$ is the tolerance factor used in calculating the tolerance interval from a sample. The sample tolerance limit is $k$ (Mean).
Summary Statements
A one-sided gamma tolerance limit computed from a sample of 1929 observations has a target coverage of 0.9000 at a 0.950 confidence level. The probability that the coverage exceeds the target value by an amount ≥ 0.0100 is 0.050. The factor k for computing the tolerance limit is 0.4785. The shape parameter of the gamma distribution is 5.

Dropout-Inflated Sample Size

<table>
<thead>
<tr>
<th>Dropout Rate</th>
<th>Sample Size</th>
<th>Dropout-Inflated Enrollment Sample Size</th>
<th>Expected Number of Dropouts</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1929</td>
<td>2412</td>
<td>483</td>
</tr>
<tr>
<td>20%</td>
<td>267</td>
<td>334</td>
<td>67</td>
</tr>
<tr>
<td>20%</td>
<td>49</td>
<td>62</td>
<td>13</td>
</tr>
</tbody>
</table>

Definitions
Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as “missing”).

N is the evaluable sample size at which the tolerance interval is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated tolerance interval.

N' is the total number of subjects that should be enrolled in the study in order to end up with N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)

D is the expected number of dropouts. D = N' - N.

This report shows the calculated sample size for each of the scenarios.

Plots Section

This plot shows the sample size versus the three values of δ.
Example 2 – Calculating $\alpha'$

Continuing Example 1, the researchers want to show the impact of various sample sizes on $\alpha'$. They decide to determine the value of $\alpha'$ for various values of $N$ between 200 and 1600, keeping the other values the same except that they set $\delta$ to 0.025.

Setup

This section presents the values of each of the parameters needed to run this example. First load the Tolerance Intervals for Gamma Data procedure window. You may then make the appropriate entries as listed below, or open Example 2 by going to the File menu and choosing Open Example Template.

<table>
<thead>
<tr>
<th>Option</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design Tab</strong></td>
<td></td>
</tr>
<tr>
<td>Solve For</td>
<td>$\alpha' = \Pr(p \geq P + \delta)$</td>
</tr>
<tr>
<td>Shape Parameter</td>
<td>5</td>
</tr>
<tr>
<td>Limit Type</td>
<td>Lower Tolerance Limit</td>
</tr>
<tr>
<td>N (Sample Size)</td>
<td>50 to 400 by 50</td>
</tr>
<tr>
<td>Proportion Covered (P)</td>
<td>0.90</td>
</tr>
<tr>
<td>Confidence Level ($1 - \alpha$)</td>
<td>0.95</td>
</tr>
<tr>
<td>Coverage Proportion Exceedance ($\delta$)</td>
<td>0.025</td>
</tr>
</tbody>
</table>

Output

Click the Calculate button to perform the calculations and generate the following output.

### Numeric Results

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Sample Size</th>
<th>Proportion Covered</th>
<th>Proportion Covered Exceedance Margin</th>
<th>$\Pr(p \geq P + \delta)$</th>
<th>$\alpha'$</th>
<th>Tolerance Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1 - \alpha$</td>
<td>N</td>
<td>P</td>
<td>$\delta$</td>
<td>$P + \delta$</td>
<td>$\delta'$</td>
<td>$k$</td>
</tr>
<tr>
<td>0.950</td>
<td>50</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.576</td>
<td>0.4398</td>
</tr>
<tr>
<td>0.950</td>
<td>100</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.349</td>
<td>0.4527</td>
</tr>
<tr>
<td>0.950</td>
<td>150</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.202</td>
<td>0.4586</td>
</tr>
<tr>
<td>0.950</td>
<td>200</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.113</td>
<td>0.4622</td>
</tr>
<tr>
<td>0.950</td>
<td>250</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.061</td>
<td>0.4647</td>
</tr>
<tr>
<td>0.950</td>
<td>300</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.033</td>
<td>0.4665</td>
</tr>
<tr>
<td>0.950</td>
<td>350</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.017</td>
<td>0.4680</td>
</tr>
<tr>
<td>0.950</td>
<td>400</td>
<td>0.900</td>
<td>0.025</td>
<td>0.9250</td>
<td>0.009</td>
<td>0.4691</td>
</tr>
</tbody>
</table>

This report shows the impact on $\alpha'$ of various sample sizes. Since the value of the Tolerance Factor $k$ is not related to $\alpha'$ or $\delta$, this report allows you to calculate $k$ for use with sample data.
This plot shows the sample size versus $\alpha'$. 

\[ \alpha' \text{ vs } N \]

$P=0.90 \delta=0.025 \text{ C.L.}=0.95 \text{ 1-Sided Gamma Tolerance Limit}$
Example 3 – Validation using Guenther (1972)

Guenther (1972) page 323 gives an example in which $R = 2.5$, $P = 0.9$, $1 - \alpha = 0.95$, $P + \delta = 0.99$, and $\alpha' = 0.05$. He obtains a sample size of 4 and a $k$ of 0.2050. Note that Guenther uses $r = 2R$ in his formulation.

Setup

This section presents the values of each of the parameters needed to run this example. First load the Tolerance Intervals for Gamma Data procedure window. You may then make the appropriate entries as listed below, or open Example 3 by going to the File menu and choosing Open Example Template.

<table>
<thead>
<tr>
<th>Option</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Tab</td>
<td></td>
</tr>
<tr>
<td>Solve For</td>
<td>Sample Size</td>
</tr>
<tr>
<td>Shape Parameter</td>
<td>2.5</td>
</tr>
<tr>
<td>Limit Type</td>
<td>Lower Tolerance Limit</td>
</tr>
<tr>
<td>Proportion Covered (P)</td>
<td>0.9</td>
</tr>
<tr>
<td>Confidence Level $(1 - \alpha)$</td>
<td>0.95</td>
</tr>
<tr>
<td>Coverage Proportion Exceedance $(\delta)$</td>
<td>0.09</td>
</tr>
<tr>
<td>$\alpha' = \Pr(p \geq P + \delta)$</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

<table>
<thead>
<tr>
<th>Confidence Level $1 - \alpha$</th>
<th>Sample Size N</th>
<th>Proportion Covered P</th>
<th>Proportion Covered Margin $\delta$</th>
<th>$P + \delta$</th>
<th>$\Pr(p \geq P + \delta)$ $\alpha'$</th>
<th>Tolerance Factor $k$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.950</td>
<td>4</td>
<td>0.9000</td>
<td>0.0900</td>
<td>0.9900</td>
<td>0.05</td>
<td>0.2051</td>
</tr>
</tbody>
</table>

PASS also calculates the sample size to be 4. The value of $k$ matches to within rounding.