

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 $100\beta\%$ of the population with probability of at least $100(1 - \alpha)\%$. 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 that 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 θ 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, δ the proportion exceedance margin, and α' 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

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

The value of k is given by

$$k = \frac{N\chi_{2R;1-P}^2}{\chi_{2RN;1-\alpha}^2}$$

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

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

The value of k is given by

$$k = \frac{N\chi_{2R;P}^2}{\chi_{2RN;\alpha}^2}$$

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

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 researchers want to investigate using a δ of 0.01, 0.02, or 0.05 with an α' of 0.05.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

```

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
    
```

Output

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

Numeric Reports

Numeric Results

```

Solve For:      Sample Size N
Interval Type:  Lower Tolerance Interval
Gamma Shape:    5
    
```

Confidence Level $1 - \alpha$	Sample Size N	Proportion of Population Covered			$\Pr(p \geq P + \delta)$ α'	Tolerance Factor k
		Value P	Exceedance Margin δ	Upper Limit $P + \delta$		
0.95	1929	0.9	0.010	0.910	0.05	0.4785
0.95	267	0.9	0.025	0.925	0.05	0.4654
0.95	49	0.9	0.050	0.950	0.05	0.4394

Tolerance Intervals for Gamma Data

- 1 - α Confidence Level. The proportion of studies with the same settings that produce tolerance intervals with a proportion covered of at least P.
- N The number of subjects.
- P The proportion of the population covered. It is the probability of being greater than the tolerance limit based on the gamma distribution.
- δ Proportion Covered Exceedance Margin. The value that is added to P to set an upper bound on the coverage at P + δ .
- P + δ The upper limit of the proportion covered, P. It is a measure of the precision (closeness) of the actual coverage to P.
- p The value of P computed from a random sample.
- α' The probability that the sample value p is greater than P + δ . It is set to a small value such as 0.05 or 0.01. $\alpha' = \Pr(p \geq P + \delta)$.
- k The tolerance factor used in calculating the tolerance interval from a sample. The sample tolerance limit is k (Mean).

Summary Statements

A single-group design will be used to obtain a one-sided 95% lower limit tolerance interval where the target proportion of the population covered is 0.9. The underlying data are assumed to follow a gamma distribution with a shape parameter value of 5. To produce a lower limit tolerance interval where the probability that the coverage (0.9) is exceeded by more than 0.01 is 0.05, 1929 subjects will be needed. The factor k for computing the tolerance limit is 0.4785.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	1929	2412	483
20%	267	334	67
20%	49	62	13

- Dropout Rate 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"). Abbreviated as DR.
- N 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' The total number of subjects that should be enrolled in the study in order to obtain 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., Wang, H., and Lohknygina, Y. (2018) pages 32-33.)
- D The expected number of dropouts. $D = N' - N$.

Dropout Summary Statements

Anticipating a 20% dropout rate, 2412 subjects should be enrolled to obtain a final sample size of 1929 subjects.

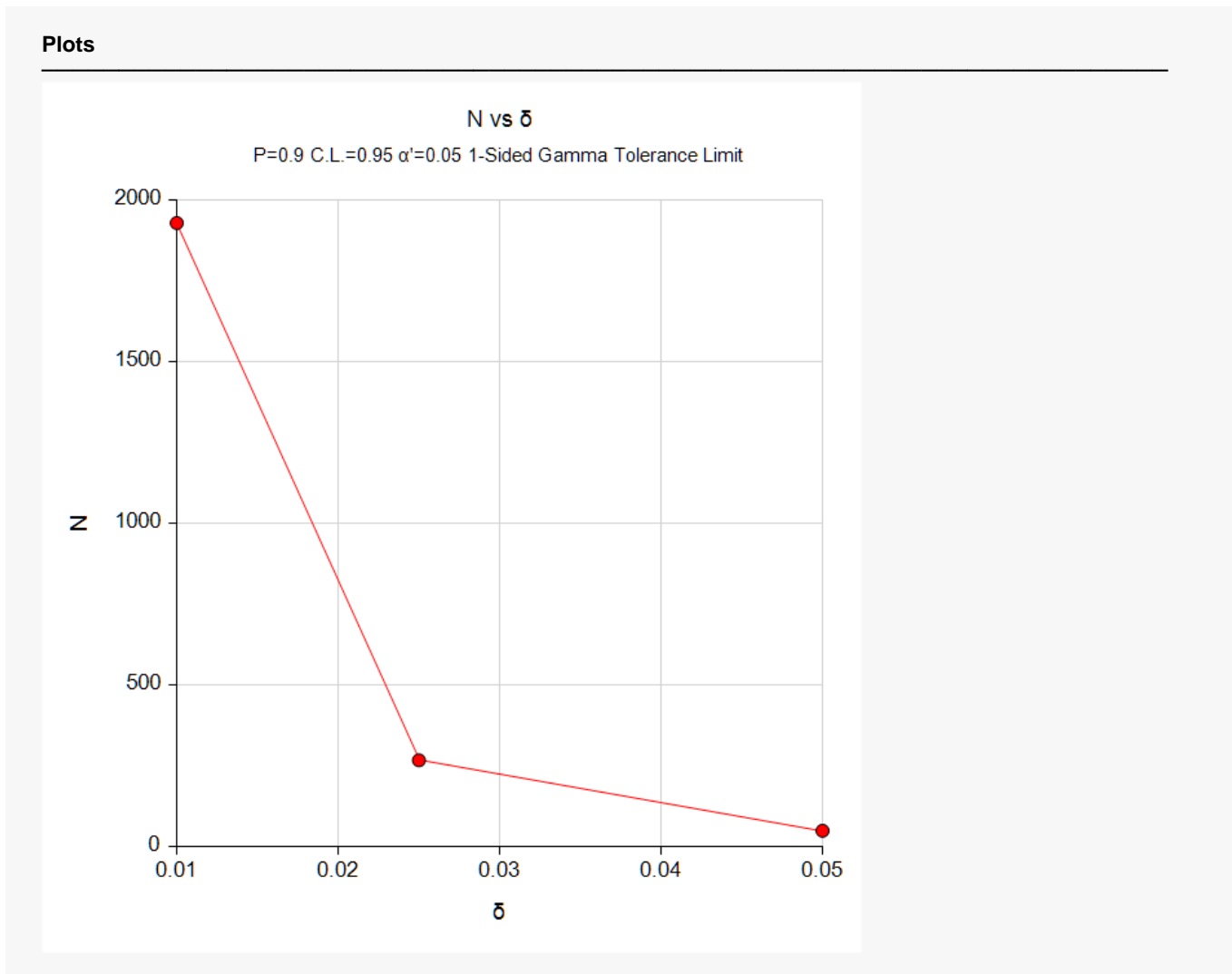
References

Guenther, William C. 1972. 'Tolerance Intervals for Univariate Distributions.' Naval Research Logistics Quarterly, Vol. 19, No. 2, Pages 309-333.
 Guenther, William C. 1977. Sampling Inspection in Statistical Quality Control. Griffin's Statistical Monographs, Number 37. London.

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

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Plots Section



This plot shows the sample size versus the three values of δ .

Example 2 – Calculating α'

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

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab	
Solve For	$\alpha' = \Pr(p \geq P + \delta)$
Shape Parameter.....	5
Limit Type	Lower Tolerance Limit
N (Sample Size).....	50 to 400 by 50
Proportion Covered (P).....	0.90
Confidence Level (1 - α).....	0.95
Coverage Proportion Exceedance (δ).....	0.025

Output

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

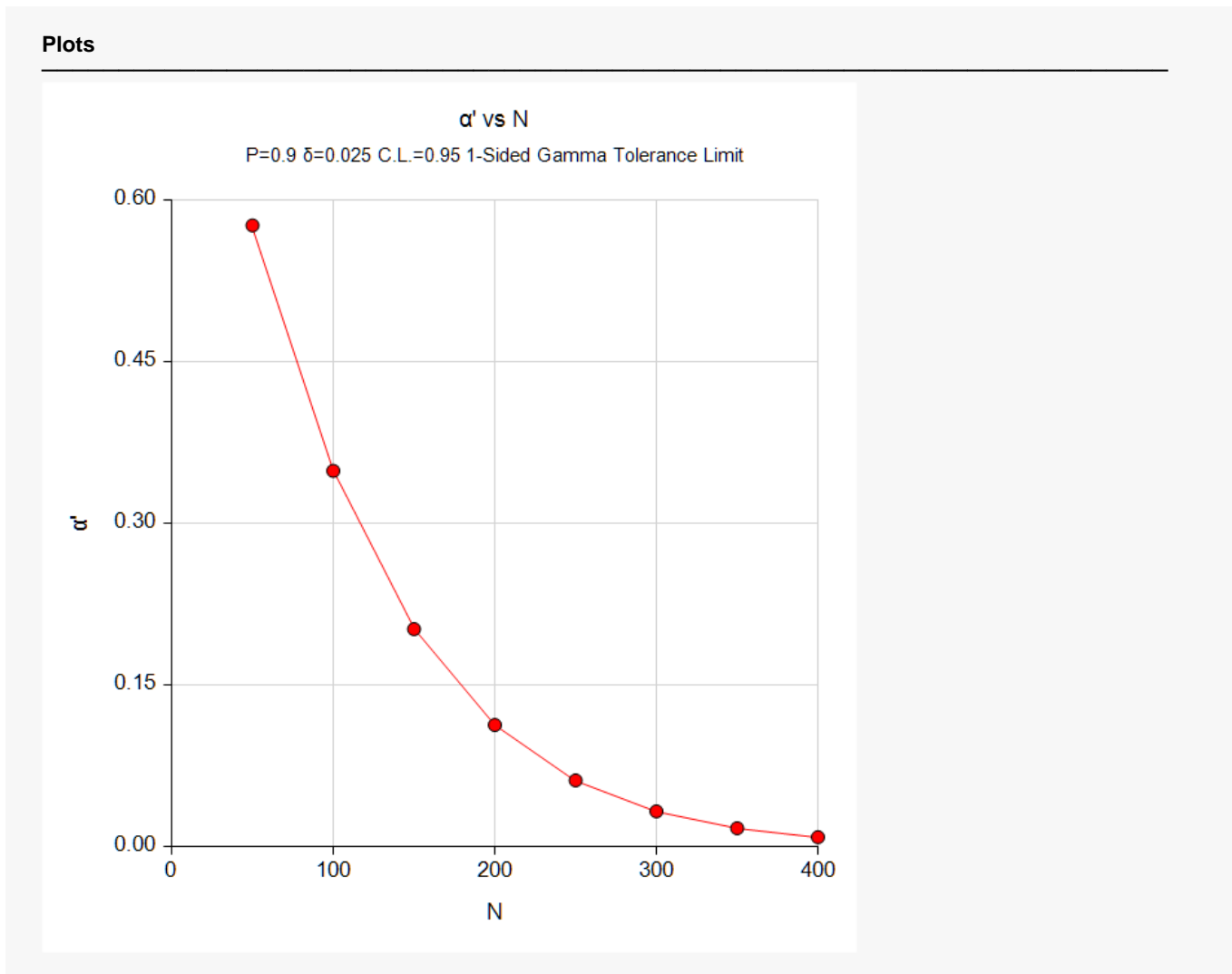
Numeric Reports

Numeric Results						
Solve For:	$\alpha' = \Pr(p \geq P + \delta)$					
Interval Type:	Lower Tolerance Interval					
Gamma Shape:	5					
Confidence Level 1 - α	Sample Size N	Proportion of Population Covered			$\Pr(p \geq P + \delta)$ α'	Tolerance Factor k
		Value P	Exceedance Margin δ	Upper Limit P + δ		
0.95	50	0.9	0.025	0.925	0.576	0.4398
0.95	100	0.9	0.025	0.925	0.349	0.4527
0.95	150	0.9	0.025	0.925	0.202	0.4586
0.95	200	0.9	0.025	0.925	0.113	0.4622
0.95	250	0.9	0.025	0.925	0.061	0.4647
0.95	300	0.9	0.025	0.925	0.033	0.4665
0.95	350	0.9	0.025	0.925	0.017	0.4680
0.95	400	0.9	0.025	0.925	0.009	0.4691

This report shows the impact on α' of various sample sizes. Since the value of the *Tolerance Factor* k is not related to α' or δ , this report allows you to calculate k for use with sample data.

Tolerance Intervals for Gamma Data

Plots Section



This plot shows the sample size versus α' .

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

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab	
Solve For	Sample Size
Shape Parameter.....	2.5
Limit Type	Lower Tolerance Limit
Proportion Covered (P).....	0.9
Confidence Level (1 - α).....	0.95
Coverage Proportion Exceedance (δ).....	0.09
$\alpha' = \Pr(p \geq P + \delta)$	0.05

Output

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

Numeric Results						
Solve For:	Sample Size N					
Interval Type:	Lower Tolerance Interval					
Gamma Shape:	2.5					
Confidence Level 1 - α	Sample Size N	Proportion of Population Covered			Pr($p \geq P + \delta$) α'	Tolerance Factor k
		Value P	Exceedance Margin δ	Upper Limit P + δ		
0.95	4	0.9	0.09	0.99	0.05	0.2051

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