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Original Research Paper

Statistical Inference of Process Capability Indices With Fuzzy Limits for Normal and Exponential Distributions

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Abstract. Statistical quality control relies on process capability indice (PCI) to quantify the ability of a process. When specification limits are modeled as fuzzy sets, conventional PCIs require fuzzification. In this paper, we present confidence intervals for PCIs, where the specification limits are fuzzy in the case of exponential distributions family by proving some theoretical results and providing a numerical example for more illustration. Also, we propose a hypothesis testing related to PCIs $C_{\tilde{p}}$ and $C'_{\tilde{p}}$ with a numerical example.

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1 Introduction

The PCI is an important tool used in examining the performance status of processes, and many researchers studied on this issue both in theory of statistical quality control and in real world applications [17]. The interval estimation for PCI is also an important issue in applications. In literature there are defined many PCIs which can be used under different statistical conditions, among them are $C_{\tilde{p}}$ and $C'_{\tilde{p}}$ [17]. After the introduction of fuzzy sets by L. A. Zadeh [31], many researchers used the idea of fuzzy sets in developing PCIs [24, 23, 30, 22]. This issue is also done in the cases where the specification limits (SLs) are fuzzy rather than real numbers [24].

There are many articles that studied confidence intervals $(1-\alpha)100\%$ of $C_{\tilde{p}}$ and $C'_{\tilde{p}}$ for the PCIs, however, in this article, we aim to apply the results of [5] to derive these confidence intervals, and we will mention those related to our study in this paper. Parchami et al. in [24, 19], discussed PCIs and derived fuzzy confidence intervals for the PCI $C_{\tilde{p}}$. They also proposed a $(1-\alpha)100\%$ confidence interval for the PCI $\widehat{C}_{\tilde{p}}$ by using fuzzy set theory. Alizadeh et al. [5] presented a general solution to obtain an unbiased confidence interval with confidence coefficient of $(1-\alpha)100\%$ in one-parameter exponential families. The use of PCI has various applications.

Saha et al. in [27] explore generalized PCI $\mathcal{C}_{py}$ under finite mixture distributions like xgamma and Akash. Using MLE and MVUE, the index is estimated and its confidence intervals are constructed via the ACI method. Monte Carlo simulations evaluate the estimators' performance, focusing on interval width and coverage probability. Real data from food and electronics industries validate its practical relevance. The paper aims to enhance PCI estimation in non-normal settings.

Kumar et al. in [16] introduces a generalized PCI $\mathcal{C}_{pyk}$ designed for discrete data following the Discrete Lindley distribution. Classical estimation methods and bootstrap techniques are used to calculate confidence intervals, and their performance is evaluated through Monte Carlo simulation. Real datasets support the practical relevance of the proposed approach. The study aims to provide a reliable tool for assessing PCI in non-normal and discrete settings.

Dey et al. in [9] investigates the *Spmk* index under the log-logistic distribution. The authors use eight statistical methods to estimate its parameters and apply three bootstrap techniques standard, percentile, and Student's t to construct confidence intervals. The performance is assessed via Monte Carlo simulation based on precision, interval width, and coverage probability. Two real-world datasets are used for validation. The study aims to recommend the most suitable estimation method for non-normal and small-sample contexts.

Kashif et al. in [12] introduces a new PCI designed for non-normal Weibull distributions. It constructs three types of bootstrap confidence intervals standard (SB), percentile (PB), and bias-corrected percentile (BCPB) for the proposed index. Using Monte Carlo simulation, the study evaluates each method's performance based on interval width and coverage probability. Results show that BCPB offers superior accuracy and efficiency. A real-world dataset on carbon fiber failure stress is analyzed to demonstrate the index's practical application. The paper aims to improve statistical assessment of PCI under non-normal conditions.

Contributions of this paper: The main contributions of this work are threefold:

1. We extend the classical PCI confidence intervals to the exponential family of distributions under fuzzy specification limits, providing exact inference without relying on large-sample approximations.

2. We develop a unified framework for both confidence intervals and hypothesis testing using pivotal quantities, which is computationally efficient and applicable for small to moderate sample sizes.

3. We provide practical guidelines for implementing the proposed method in real industrial settings, including step-by-step procedures for constructing fuzzy specification limits and interpreting the results operationally.

Unlike the simulation-based Monte Carlo approach of [11], our method offers exact inference using pivotal quantities, which provides advantages for small to moderate sample sizes where simulation-based methods may be less reliable.

In summary, the practical motivation for this study stems from real-world quality control scenarios where specification limits are inherently vague due to measurement errors, subjective judgments, or gradual quality degradation. The proposed fuzzy framework provides a realistic and flexible alternative to classical crisp limits, enabling quality engineers to make more informed decisions. This practical relevance is further demonstrated through detailed examples from pharmaceutical and mechanical industries in Section 2.1, along with step-by-step procedures for determining fuzzy specification limits in practice.

For further study, one can refer to some sources such as [28, 32, 8, 29, 7, 25, 1, 20, 2, 13, 3, 6, 4, 26].

This research is done where the specification limits (SLs) are fuzzy, and the process distribution is either normal or exponential and we will find the estimates of PCIs $\widehat{C}_{\tilde{p}}$ and $\widehat{C}'_{\tilde{p}}$. To achieve this aim, we use the research of [5] that presented a general solution to obtain an unbiased confidence interval with confidence coefficient of $(1-\alpha)100\%$ in one-parameter exponential families.

In section 2 of this article, the two process capability indices (PCIs) for $\widehat{C}_{\tilde{p}}$ and $\widehat{C}'_{\tilde{p}}$ are introduced and reformulated by considering the constraints imposed by fuzzy technical specifications. In section 3, presents the confidence intervals associated for $\widehat{C}_{\tilde{p}}$ and $\widehat{C}'_{\tilde{p}}$. Also, in section 4, presents the hypothesis testing for PCIs $\widehat{C}_{\tilde{p}}$ and $\widehat{C}'_{\tilde{p}}$. Finally, in section 5, provides a simulated data example to illustrate the practical application of the concepts discussed throughout the article.

2 Preliminaries

2.1 Practical motivations and determination of fuzzy specification limits

In many real-world quality control problems, specification limits are not crisp. Several factors, such as measurement uncertainty, human judgment, or gradual quality degradation, cause the boundary between acceptable and unacceptable to be vague rather than sharp. In such cases, fuzzy specification limits provide a more realistic and flexible framework than classical crisp limits.

Example from pharmaceutical industry (tablet compression process): In tablet compression processes, a temperature limit of 100°C is often interpreted as "approximately 100°C" due to sensor accuracy (e.g., ±1°C) or operator discretion. Declaring a batch at 101°C as "unacceptable" while accepting 99°C is unrealistic when the measurement error itself is ±1°C. In such cases, a fuzzy specification limit such as a triangular fuzzy number $(99, 100, 101)$ provides a more realistic representation. A batch at 100.5°C would have a membership degree of 0.5, reflecting partial acceptability rather than a binary pass/fail decision. This gradual transition between acceptable and unacceptable quality is exactly what fuzzy specification limits are designed to capture, and it directly motivates the need for the fuzzy PCI framework proposed in this paper.

Example from automotive industry (piston ring manufacturing): In the production of piston rings for internal combustion engines, the nominal diameter is specified as 100 ± 0.5 mm. However, due to thermal expansion during operation, measurement uncertainty, and wear, the boundary between acceptable and unacceptable dimensions is not sharp. A ring measuring 100.4 mm is not suddenly "bad" compared to 99.6 mm. Instead, quality engineers often use linguistic specifications such as "close to 100 mm" which are inherently fuzzy. By modeling the specification limit as a trapezoidal fuzzy number $(99.5, 99.8, 100.2, 100.5)$, the gradual transition between acceptable and unacceptable quality is accurately captured.

Example from nanotechnology (lipid-based nanoparticles for drug delivery): In the development of lipid-based nanoparticles for targeted cancer therapy, stability is assessed by the time (in hours) that nanoparticles remain intact after reconstitution. Instability is indicated if aggregation or drug loss occurs between 10 and 48 hours, while overstabilization (120-170 hours) may delay drug release. These thresholds are not absolute; a batch at 49 hours is not significantly different from one at 47 hours. By using fuzzy lower and upper specification limits (e.g., $\widetilde{LSL} = (10, 20, 30)$ and $\widetilde{USL} = (150, 170, 190)$), the inherent uncertainty and gradual transitions in stability are more realistically modeled.

How to determine fuzzy specification limits in practice: There are three practical methods for constructing fuzzy specification limits:

1. **Expert knowledge:** Quality engineers define a fuzzy number

(e.g., a triangular fuzzy number $(95, 100, 105)$ for a nominal limit of 100°C) based on their experience and process understanding. The three parameters represent the minimum, most likely, and maximum acceptable values.

2. **Measurement system analysis (MSA):** The uncertainty of measurement instruments, typically expressed as a standard deviation or confidence interval, is converted into a fuzzy interval. For example, if a gauge has a known measurement error of $\pm\delta$, the crisp limit L is replaced by a fuzzy limit with support $[L-\delta, L+\delta]$.

3. **Conversion of linguistic rules:** Existing linguistic statements from standards or manuals (e.g., "the temperature should remain close to 100°C") are translated into mathematical fuzzy limits using membership functions determined by domain experts.

Step-by-step procedure for practitioners:

1. Step 1: Identify whether the specification limit is inherently crisp (e.g., legal limit) or vague (e.g., due to measurement error or subjective judgment).

2. Step 2: If vague, choose one of the three methods above to construct a triangular or trapezoidal fuzzy number representing the limit.

3. Step 3: Use the proposed formulas in Sections 3 and 4 to compute fuzzy confidence intervals and hypothesis tests.

4. Step 4: Interpret the results using the operational guidelines provided in Section 5.3.

Therefore, the proposed method is particularly useful when the boundary between acceptable and unacceptable quality is not crisp due to measurement error, subjective judgment, or gradual equipment wear. By explicitly modeling such situations with fuzzy specification limits, our approach provides a more realistic framework for process capability analysis in practical quality control settings.

2.2 Justification for focusing on the exponential distribution family and generalizability of the proposed method

The exponential distribution family encompasses a broad class of distributions that play a central role in statistical quality control and reliability analysis. This family includes the exponential, gamma, Weibull (with fixed shape parameter), inverse Gaussian, and chi-square distributions, among others. These distributions are routinely used to model time-to-event data, waiting times, failure rates, and product lifetimes.

Why the exponential family? The primary justification for restricting attention to this family is mathematical tractability combined with practical relevance. For distributions belonging to the exponential family, the likelihood function takes a convenient form that admits sufficient statistics of fixed dimension. As a result, many process capability indices (PCIs) have closed-form expressions, enabling exact statistical inference without relying on asymptotic approximations. This is particularly advantageous when sample sizes are small or moderate — a common scenario in many quality control applications where data collection is expensive or time-consuming.

Generalizability of the proposed method. We explicitly discuss the extent to which our method can be generalized:

- **Where generalization is possible:** The conceptual framework of fuzzy specification limits and the associated PCI estimators can be extended to other continuous distributions, including the normal, log-normal, and logistic distributions, provided that the necessary pivotal quantities are available or reliable asymptotic approximations can be derived.

- **Where generalization is not straightforward:** For distributions that do not belong to the exponential family — particularly those lacking sufficient statistics or having irregular likelihood surfaces — the inferential approach developed in this paper may not apply directly. In such cases, computationally intensive methods such as parametric bootstrapping, nonparametric inference, or Bayesian approaches would be required. These extensions are beyond the scope of the present work but represent promising directions for future research.

Practical recommendation for practitioners using non-exponential distributions: For quality engineers working with non-exponential processes (e.g., normal or lognormal), we recommend using the bootstrap version of our method, where the fuzzy limits are preserved but the pivotal quantity is replaced by a bootstrap distribution. A detailed bootstrap procedure is outlined as a future research direction in Section 6.

In summary, our focus on the exponential family allows us to develop a rigorous, analytically tractable foundation for fuzzy process capability inference. The proposed framework is intentionally designed with modularity in mind, so that future work can adapt it to other distributional settings as needed.

2.3 Fuzzy and capability indices

In this subsection, we review PCIs for processes with normal and exponential distributions.

Definition 2.1. The PCI for a process with a normal distribution with a known mean μ and unknown variance σ^2, is defined $C_p = \frac{USL-LSL}{6\sigma}$, where USL and LSL are the upper and lower technical specification, respectively, and σ denotes the standard deviation of the process [14, 15].

Definition 2.2. The PCI ${C_p}'$ is defined ${C_p}' = \frac{USL-LSL}{\xi_{1-\alpha}-\xi_\alpha}$, where ξ_α is the αth quantile of X obtained from the equation $P(X \leq \xi_\alpha) = \alpha$. As a special case, when the process is normal then $\alpha = 0.0013$ and ${C_p}' = C_p$ [14, 15].

Remark 2.3. In an exponential process with the pdf $f_X(x) = \theta e^{-\theta x}; x > 0$, the PCI ${C_p}'$ obtaines as follows [10]:

$$
{C_p}' = \frac{\theta(USL - LSL)}{\ln\left(\frac{1-\alpha}{\alpha}\right)},
$$

since the αth quantile of exponential distribution is equal to $\xi_\alpha = -\frac{1}{\theta}\ln(1-\alpha)$.

Note: In practice, α is taken as a small positive number (typically $\alpha < 0.5$), ensuring that $\ln\left(\frac{1-\alpha}{\alpha}\right) > 0$ and the PCI is well-defined. Values $\alpha \geq 0.5$ correspond to quantiles at or below the median and are not relevant for process capability analysis.

In the following, we present some of the fuzzy notions used in this paper. Let $\mathbb{R}$ be the set of all real numbers and $F(\mathbb{R}) = \{\widetilde{A} | \widetilde{A} : \mathbb{R} \to [0,1]\}$. The β-cut of $\widetilde{A} \in F(\mathbb{R})$ is the crisp set $\widetilde{A}[\beta] = \{x \in \mathbb{R} | \widetilde{A}(x) \geq \beta\}$, for any $\beta \in [0,1]$. Some more basic definitions are quoted from [19].

Definition 2.4. a) Fuzzy set $\widetilde{USL} \in F(\mathbb{R})$ is called an upper fuzzy specification limit, if $\widetilde{USL}$ is a non-increasing function, and there exists $u_1 \in R$ such that $\widetilde{USL}(x) = 1$ for $x \leq u_1$, and $F_U(\mathbb{R})$ denote the set of all $\widetilde{USL}$.
b) Fuzzy set $\widetilde{LSL} \in F(\mathbb{R})$ is called an lower fuzzy specification limit, if $\widetilde{LSL}$ is a non-decreasing function, and there exists $l_1 \in \mathbb{R}$ such that $\widetilde{LSL}(x) = 1$ for $x \geq l_1$, and $F_L(\mathbb{R})$ denote the set of all $\widetilde{LSL}$.

Definition 2.5. Let $\widetilde{USL} \in F_U(\mathbb{R})$ and $\widetilde{LSL} \in F_L(\mathbb{R})$ such that $l_1 \leq u_1$. Then

$$\widetilde{USL} \ominus \widetilde{LSL} = \int_0^1 g(\beta)(u_\beta - l_\beta)d\beta$$

is called the subtraction of $\widetilde{USL}$ and $\widetilde{LSL}$, in which $\widetilde{USL}[\beta] = (-\infty, u_\beta]$ and $\widetilde{LSL}[\beta] = [l_\beta, +\infty)$ for any $\beta \in (0,1]$. Here, u_0 and l_0 are finite real numbers and g is a non-decreasing function on $[0,1]$ with $g(0) = 0$ and $\int_0^1 g(\beta)d\beta = 1$ [10, 24].

Theorem 2.6. *Let $\widetilde{LSL}$ and $\widetilde{USL}$ be two fuzzy numbers with the following membership functions [21, 18]:*

$$\widetilde{LSL}_L(x) = \begin{cases} 0 & x < l_0, \\ \frac{x-l_0}{l_1-l_0} & l_0 \leq x < l_1, \\ 1 & l_1 \leq x, \end{cases}$$

$$\widetilde{USL}_L(x) = \begin{cases} 1 & x < u_1, \\ \frac{x-u_0}{u_1-u_0} & u_1 \leq x < u_0, \\ 0 & u_0 \leq x \end{cases}$$

and $g(\beta) = (m+1)\alpha^m$, *then*

$$\widetilde{USL} \ominus \widetilde{LSL} = \frac{m+1}{m+2}\left[(u_1 - l_1) + (l_0 - u_0)\right] + (u_0 - l_0)$$

Proof. See reference [21, 18].
□

Considering Definition 2.1 and Definition 2.5,two indices given in Definition 2.2 and Remark 2.3 are extended for the case of fuzzy SLs, in below.

Definition 2.7. a) According to Definitions 2.1 and 2.5, the index $C_{\tilde{p}}$ is defined as follows [21]:

$$C_{\tilde{p}} = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{6\sigma},$$

b) According to Remark 2.3 and Definition 2.5, index $C_{\tilde{p}}{}'$ is defined as follows [21]:

$$C_{\tilde{p}}{}' = \frac{\theta\left(\widetilde{USL} \ominus \widetilde{LSL}\right)}{ln\left(\frac{1-\alpha}{\alpha}\right)}.$$

The following two lemmas present two point estimates for the PCIs $C_{\tilde{p}}$ and $C_{\tilde{p}}{}'$.

Lemma 2.8. *Let* $\underline{X} = (X_1, ..., X_n)$ *be a random sample from a normal process with known mean* μ *and unknown variance* σ^2*. Then the maximum likelihood estimation (MLE) of* $C_{\tilde{p}}$ *is:*

$$\widehat{C}_{\tilde{p}} = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{6S_b},$$

where $S_b^2 = \frac{1}{n}\sum_{i=1}^{n}(X_i - \overline{X})^2$ *is the MLE (biased) of* σ^2*.*

Proof. The only parameter that must be estimated in $C_{\tilde{p}}$ is σ, and in the normal process it is obvious that MLE of σ^2, $S_b^2 = \frac{1}{n}\Sigma_{i=1}^{n}(X_i - \overline{X})^2$ is biased estimator. So, according to the invariant property of MLE, it can be concluded that the MLE of the $C_{\tilde{p}}$ index is $\widehat{C}_{\tilde{p}} = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{6S_b}$. □

Lemma 2.9. *Let* $\underline{X}$ *be a random sample from an exponential process with unknown mean* $\dfrac{1}{\theta}$*. Then the MLE of the* $C_{\tilde{p}}{}'$ *index is [10]:*

$$\widehat{C}'_{\tilde{p}} = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{\overline{X} \ln\left(\frac{1-\alpha}{\alpha}\right)}.$$

Proof. The only parameter that must be estimated in $C'_{\tilde{p}}$ is θ, and it is obvious that in the exponential process, $MLE(\theta) = \frac{1}{\overline{X}}$. So, according to the invariant property of maximum likelihood estimators, it can be concluded that the MLE of the $C'_{\tilde{p}}$ index is $\widehat{C}'_{\tilde{p}} = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{\overline{X} \ln\left(\frac{1-\alpha}{\alpha}\right)}$. □

Now, we will use some of the results obtained in [5], which will be applied in constructing confidence intervals for the PCIs given in Definition 2.2 and Remark 2.3.

Let the one-parameter exponential families be specified by the pdf

$$f_X(x;\theta) = k(\theta)l(x)e^{-c(\theta)d(x)}; \qquad x \in \mathbb{R}, \quad \theta \in \Theta,$$

where $k(.), c(.) > 0$ are functions of θ, and both $l(.)$ and $d(.)$ are functions of x [5].

Lemma 2.10. *Let* $\underline{X}$ *denote a random sample drawn from an exponential distribution with pdf (1).*

(i) *The statistic* $T(\underline{X}) = \Sigma_{i=1}^{n} d(X_i)$ *serves as a complete, sufficient, and minimal statistic for* $c(\theta)$*.*

(ii) *When* $T(\underline{X})$ *follows a gamma distribution with parameters* $\frac{\upsilon}{2}$ *and* $c(\theta)$*, the transformed quantity*

$$Q(\theta) = 2c(\theta)T(\underline{X}) = 2c(\theta)\Sigma_{i=1}^{n} d(x_i)$$

becomes a pivotal variable. In this case, $Q(\theta)$ *has a chi-square distribution with* υ *degrees of freedom, denoted by* χ^2_{υ} *[5].*

2.4 Connecting preliminary lemmas, pivotal quantities, and final inference

To make the mathematical development more transparent, we explicitly outline the logical flow from the lemmas to the confidence intervals and hypothesis tests.

Step 1: Preliminary lemmas (Section 2). Lemmas 2.9 and 2.10 provide the distributional properties of the estimators. Specifically, Lemma 2.10 shows that for the exponential distribution, the statistic $T(\mathbf{X}) = \sum_{i=1}^{n} X_i$ is complete and sufficient, and that the pivotal quantity $Q(\theta) = 2\theta T(\mathbf{X})$ follows a chi-square distribution with $2n$ degrees of freedom, i.e., $Q(\theta) \sim \chi^2_{2n}$.

Step 2: Pivotal quantity as the bridge. The quantity $Q(\theta) = 2\theta \sum_{i=1}^{n} X_i$ is pivotal because its distribution (χ^2_{2n}) does not depend on the unknown parameter θ. This pivotal quantity is the bridge between the lemmas and the final inference.

Step 3: Derivation of confidence intervals (Section 3). Because $Q(\theta)$ is pivotal, we can find constants a and b such that $P(a \leq Q(\theta) \leq b) = 1 - \alpha$. Substituting $Q(\theta) = 2\theta T(\mathbf{X})$ and solving for the fuzzy capability index $C'_{\vec{p}}$ directly yields the confidence interval in Theorem 3.2. No new assumptions are introduced at this stage.

Step 4: Derivation of hypothesis tests (Section 4). For hypothesis testing, the same pivotal quantity is inverted. Under the null hypothesis $H_0 : C'_{\vec{p}} \leq C_0$, we obtain $\theta_0 = \frac{C_0 \ln(\frac{1-\alpha}{\alpha})}{\widetilde{USL} \ominus \widetilde{LSL}}$. The test statistic $\chi^2_0 = 2\theta_0 \sum_{i=1}^{n} X_i$ follows a χ^2_{2n} distribution under H_0, leading directly to the rejection regions in Theorem 4.2.

Summary of the logical chain for the reader:

$$\text{Lemma 2.10} \longrightarrow \text{Pivotal quantity } Q(\theta) = 2\theta T(\mathbf{X}) \sim \chi^2_{2n} \longrightarrow$$

$$\begin{cases} \text{Confidence intervals (Theorem 3.2)} \\ \text{Hypothesis tests (Theorem 4.2)} \end{cases}$$

Each step follows directly from the previous one, and the same pivotal quantity is used for both estimation and testing. This transparent structure ensures that the reader can verify the validity of the final results without ambiguity.

3 Confidence Intervals for $C_{\tilde{p}}$ and $C'_{\tilde{p}}$

In this section, we use the pivotal quantity $Q(\theta) = 2\theta T(\mathbf{X}) \sim \chi^2_{2n}$ derived in Lemma 2.10 and the logical chain outlined in Section 2.4 to construct confidence intervals for $C_{\tilde{p}}$ and $C'_{\tilde{p}}$. The same pivotal quantity is used as the foundation for both confidence intervals and hypothesis tests, ensuring consistency and transparency in the inferential framework.

Definition of unbiased confidence interval: A confidence interval is said to be unbiased if the coverage probability is at least $1-\alpha$ for all parameter values and the probability of covering false values is less than or equal to the probability of covering the true value. In the context of this paper, the constants a and b are chosen to satisfy this property.

Before stating the theorems, we define the constants a and b. Let $Q(\theta)$ be a pivotal quantity with $Q(\theta) \sim \chi^2_\nu$. The constants a and b satisfy $P(a \leq Q(\theta) \leq b) = 1-\alpha$ and are chosen to minimize the interval length (unbiased confidence interval). These constants can be obtained from the chi-square distribution tables or computed numerically.

Theorem 3.1. *Let $\underline{X}$ be a random sample from a normal process with known mean μ and unknown variance σ^2. Then, the general confidence interval with $1-\alpha$ confidence coefficient for the PCI $C_{\tilde{p}}$ is as follows:*

$$\left(\widehat{C}_{\tilde{p}}\sqrt{\frac{a}{n}}, \widehat{C}_{\tilde{p}}\sqrt{\frac{b}{n}}\right).$$

Proof. As the process has a normal distribution with known mean μ and unknown variance σ^2. Note that the normal distribution with known mean μ and unknown variance σ^2 is a one-parameter exponential family with $c(\sigma) = \frac{1}{\sigma^2}$ and $T(X) = \frac{1}{2}\sum_{i=1}^n (X_i-\mu)^2$. Therefore, by Eq.(1), $c(\sigma) = \frac{1}{\sigma^2}$ and $T(X) = \frac{1}{2}\sum_{i=1}^n (X_i-\mu)^2$. By using [5], the general confidence interval with $(1-\alpha)$ confidence coefficient for the index $c(\sigma)$ is as follows:

$$\left(\frac{a}{nS_b^2}, \frac{b}{nS_b^2}\right).$$

Therefore, $\left(\widehat{C}_{\tilde{p}}\sqrt{\frac{a}{n}}, \widehat{C}_{\tilde{p}}\sqrt{\frac{b}{n}}\right)$ is a confidence interval for $C_{\tilde{p}}$ with $1-\alpha$ confidence coefficient. $\square$

Theorem 3.2. *Let $\underline{X}$ be a random sample from an exponential process with mean $\frac{1}{\theta}$. Then, the general confidence interval with $1-\alpha$ confidence coefficient for the PCI $C'_{\tilde{p}}$ is as follows:*

$$\left(\widehat{C}'_{\tilde{p}}\left(\frac{a}{2n}\right), \widehat{C}'_{\tilde{p}}\left(\frac{b}{2n}\right)\right).$$

Proof. As the process has an exponential distribution with mean $\frac{1}{\theta}$, by Eq.(1), $c(\theta) = \theta$ and $T(X) = \sum_{i=1}^{n} X_i$. By using [5], the general confidence interval with $1-\alpha$ confidence coefficient for the index $c(\theta)$ is as follows:

$$\left(\frac{a}{2n\overline{X}}, \frac{b}{2n\overline{X}}\right),$$

Therefore, $\left(\widehat{C}'_{\tilde{p}}\left(\frac{a}{2n}\right), \widehat{C}'_{\tilde{p}}\left(\frac{b}{2n}\right)\right)$ is a confidence interval for $C'_{\tilde{p}}$ with $1-\alpha$ confidence coefficient. $\square$

Theorem 3.3. *Let $\underline{X}$ be a random sample from a normal process with known mean μ and unknown variance σ^2. Then, the unbiased confidence interval with $1-\alpha$ confidence coefficient can be calculated for the PCI $C_{\tilde{p}}$, where the constants a and b are obtained in such a way that the following relation hold:*

$$\begin{cases} \int_a^b \frac{1}{\Gamma(\frac{n}{2})2^{\frac{n}{2}}} q^{\frac{n}{2}-1} e^{-\frac{q}{2}} dq = 1-\alpha \\ \\ b^{\frac{n}{2}} e^{-\frac{b}{2}} = a^{\frac{n}{2}} e^{-\frac{a}{2}}. \end{cases}$$

Proof. As the process has a normal distribution with known mean μ and unknown variance σ^2, by Eq.(1), $c(\sigma) = \frac{1}{\sigma^2}$ and $T(X) = \frac{1}{2}\sum_{i=1}^{n}(X_i - \mu)^2$. Therefore, $Q = 2c(\sigma)T(X) = \frac{nS_b^2}{\sigma^2} \sim \chi_n^2$. By using [5], the unbiased confidence interval with $1-\alpha$ confidence coefficient can be calculated for the index $c(\sigma)$ with conditions for a and b is obtained. Then the proof is completed. $\square$

Theorem 3.4. *Let $\underline{X}$ be a random sample from an exponential process with mean $\frac{1}{\theta}$. Then, the unbiased confidence interval with $1-\alpha$ confidence coefficient can be calculated for the PCI $C_{\tilde{p}}$, where the constants a and b are obtained in such a way that the following relation hold:*

$$\begin{cases} \int_a^b \frac{1}{\Gamma(n)2^n} q^{n-1} e^{-\frac{q}{2}} dq = 1-\alpha \\ \\ b^n e^{-\frac{b}{2}} = a^n e^{-\frac{a}{2}}. \end{cases}$$

Proof. As the process has an exponential distribution with mean $\frac{1}{\theta}$, by Eq.(1), $c(\theta) = \theta$ and $T(X) = \sum_{i=1}^n X_i$. Therefore, $Q = 2c(\theta)T(X) = 2\theta \sum_{i=1}^n X_i \sim \chi^2_{2n}$. By using [5], the unbiased confidence interval with $1-\alpha$ confidence coefficient can be calculated for the index $c(\theta)$ with the conditions for a and b is obtained. Then the proof is completed. $\square$

4 Hypothesis Tests for $C_{\tilde{p}}$ and $C'_{\tilde{p}}$

In this section of the paper, we aim to conduct hypothesis testing for PCIs $C_{\tilde{p}}$ and $C'_{\tilde{p}}$, which have been introduced earlier in this study. To achieve this, we first need to present the hypotheses for each indicator, and subsequently introduce the corresponding test statistics for them.

Theorem 4.1. *If a process follows a normal distribution with parameters μ and σ, then the following hypothesis tests are equivalent.*

$$\begin{cases} H_0 : C_{\tilde{p}} \le C_0 \\ H_1 : C_{\tilde{p}} > C_0 \end{cases} \equiv \begin{cases} H_0 : \sigma \ge \sigma_0 \\ H_1 : \sigma < \sigma_0 \end{cases}$$

$$\begin{cases} H_0 : C_{\tilde{p}} \ge C_0 \\ H_1 : C_{\tilde{p}} < C_0 \end{cases} \equiv \begin{cases} H_0 : \sigma \le \sigma_0 \\ H_1 : \sigma > \sigma_0 \end{cases}$$

$$\begin{cases} H_0 : C_{\tilde{p}} = C_0 \\ H_1 : C_{\tilde{p}} \ne C_0 \end{cases} \equiv \begin{cases} H_0 : \sigma = \sigma_0 \\ H_1 : \sigma \ne \sigma_0 \end{cases}$$

Also, their test statistic is expressed as $\chi^2_0 = \frac{(n-1)S^2}{\sigma^2_0}$ where $\sigma^2_0 = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{6C_0}$

Proof. according to the Definition 2.7, the null hypothesis for the first hypothesis test is formulated as follows:

$$\frac{\widetilde{USL} \ominus \widetilde{LSL}}{6\sigma} \leq C_0$$

then, $\sigma \geq \sigma_0$ where $\sigma_0^2 = \frac{\widetilde{USL} \ominus \widetilde{LSL}}{6C_0}$. In a similar manner, the same approach is employed for the remaining two hypothesis tests. Now, according to the assumption of Theorem 4.1, the process follows a normal distribution. Therefore,

$$\frac{(n-1)\, S^2}{\sigma^2} \sim \chi^2_{n-1},$$

then, test statistic is $\chi_0^2 = \frac{(n-1)s^2}{\sigma_0^2}$. $\square$

Theorem 4.2. *If a process follows an exponential distribution with parameter θ, then the following hypothesis tests are equivalent.*

$$\begin{cases} H_0 : C'_{\tilde{p}} \leq C_0 \\ H_1 : C'_{\tilde{p}} > C_0 \end{cases} \equiv \begin{cases} H_0 : \theta \leq \theta_0 \\ H_1 : \theta > \theta_0 \end{cases}$$

$$\begin{cases} H_0 : C'_{\tilde{p}} \geq C_0 \\ H_1 : C'_{\tilde{p}} < C_0 \end{cases} \equiv \begin{cases} H_0 : \theta \geq \theta_0 \\ H_1 : \theta < \theta_0 \end{cases}$$

$$\begin{cases} H_0 : C'_{\tilde{p}} = C_0 \\ H_1 : C'_{\tilde{p}} \neq C_0 \end{cases} \equiv \begin{cases} H_0 : \theta = \theta_0 \\ H_1 : \theta \neq \theta_0 \end{cases}$$

Also, their test statistic is expressed as $\chi_0^2 = 2\theta_0 \Sigma_{i=1}^n x_i$ *where* $\theta_0 = \frac{C_0 ln\left(\frac{1-\alpha}{\alpha}\right)}{\widetilde{USL} \ominus \widetilde{LSL}}$

Proof. according to the Definition 2.7, the null hypothesis for the first hypothesis test is formulated as follows:

$$\frac{\theta \left(\widetilde{USL} \ominus \widetilde{LSL}\right)}{ln\left(\frac{1-\alpha}{\alpha}\right)} \leq C_0$$

then, $\theta \leq \theta_0$ where $\theta_0 = \frac{C_0 ln\left(\frac{1-\alpha}{\alpha}\right)}{\widetilde{USL} \ominus \widetilde{LSL}}$. In a similar manner, the same approach is employed for the remaining two hypothesis tests. Now, according to the assumption of Theorem 4.1, the process follows a exponential distribution. Therefore,

$$2\theta \Sigma_{i=1}^{n} X_i \sim \chi^2_{2n},$$

then, test statistic is $\chi^2_0 = 2\theta_0 \Sigma_{i=1}^{n} x_i$. $\square$

5 Case Study in Dairy Industries

In this section, in order to enhance the understanding of the concepts discussed in this paper, we provide practical examples related to PCI $C'_{\tilde{p}}$. Specifically, we illustrate the construction of confidence intervals and the formulation of hypothesis tests for this indicator.

Example 5.1. A pharmaceutical nanotechnology company is developing lipid-based nanoparticles for targeted cancer drug delivery. These nanoparticles are engineered to remain stable and retain their drug payload for a defined period after reconstitution. The formulation incorporates PEGylated lipids to extend circulation time and prevent premature degradation. Instability is indicated if the nanoparticles aggregate or lose drug content between 10 and 48 hours, which risks reducing therapeutic efficacy. Conversely, if they remain intact between 120 and 170 hours, it may suggest over-stabilization, potentially leading to delayed drug release and off-target effects. To assess this, we analyze 50 simulated data points representing the number of hours each batch remains stable under controlled conditions after preparation.

$$36, 40, 42, 45, 50, 60, 70, 80, 90, 100, 110, 120, 60, 70, 80, 90, 100, 110, 120, 60,$$
$$70, 80, 90, 100, 110, 120, 60, 70, 80, 90, 100, 110, 120, 60, 70, 80, 90, 100, 110, 120,$$
$$130, 140, 150, 130, 140, 150, 130, 140, 150, 130$$

The significance of this example lies in demonstrating how a real challenge in advanced drug delivery can be addressed through statistical and quality control methods. Lipid-based nanoparticles are central to modern therapies, and their stability directly influences both drug efficacy and patient safety. Since experimental data often exhibit variability and acceptance thresholds (such as 48 and 120 hours) are not absolute in practice, this case provides a strong rationale for adopting innovative approaches such as fuzzy logic. By incorporating fuzzification, decision-making becomes more flexible and realistic: small fluctuations in results no longer cause abrupt changes in classification, and fuzzy capability indices provide a more accurate evaluation of process performance. Thus, this example underscores the value of integrating statistical theory with practical applications in nanoparticle drug delivery systems. In evaluating the stability of lipid-based nanoparticles, fuzzy logic proves highly beneficial because acceptance thresholds (48 and 120 hours) are not absolute in practice, and experimental data often involve variability and uncertainty. Fuzzification introduces gradual membership functions that capture this uncertainty and prevent abrupt classifications, ensuring that minor differences in results (e.g., 47 vs. 49 hours) do not lead to unrealistic shifts in decision-making. Moreover, fuzzy logic establishes more flexible and realistic criteria for clinical and industrial applications, where slight deviations from defined limits may still be acceptable. Finally, fuzzy process capability indices such as $\widehat{C}'_{\tilde{p}}$ offer a more accurate and robust assessment of process performance compared to classical indices, making fuzzification a valuable approach for quality evaluation in nanoparticle drug delivery systems. Membership function for the fuzzy lower limit of the technical specification ($\widetilde{LSL}_L$) is using Theorem 2.6 as follows:

$$\widetilde{LSL}_L(x) = \begin{cases} 0 & x < 10, \\ \frac{x-10}{38} & 10 \le x < 48, \\ 1 & 48 \le x. \end{cases}$$

Also, membership function for the fuzzy upper limit of the technical specification ($\widetilde{USL}_L$) is is using Theorem 2.6 as follows:

$$\widetilde{USL}_L(x) = \begin{cases} 1 & x < 120, \\ \frac{x-170}{-50} & 120 \le x < 170, \\ 0 & 170 \le x. \end{cases}$$

Then to find the values l_β and u_β we need the β-cutes for $\widetilde{LSL}_L$ and $\widetilde{USL}_L$. Therefore

$$\widetilde{LSL}_L[\beta] = [10 + 38\beta, \infty) \qquad , \qquad \widetilde{USL}_L[\beta] = (-\infty, 170 - 50\beta]$$

Therefore by using Theorem 2.6

$$\widetilde{USL} \ominus \widetilde{LSL} = 160 - 88\left(\frac{m+1}{m+2}\right)$$

For ten randomly selected values of α and the corresponding values of m, the index $\widehat{C}'_{\tilde{p}}$ and the confidence intervals with equal tails $(1-\alpha)$ were computed using R software. The results indicate that the estimated values of the capability index $\widehat{C}'_{\tilde{p}}$ consistently fall within their respective confidence intervals, which confirms the validity and robustness of the proposed methodology under different statistical conditions. These findings not only reinforce the reliability of the results but also provide additional empirical evidence for the analysis of confidence interval of the PCI for Exponential distribution. Consequently, it can be concluded that the proposed approach demonstrates strong potential in evaluating and interpreting process capability indices and may serve as a practical tool in statistical studies.

The estimated values for the capability index $C'_{\tilde{p}}$ lie within their respective confidence intervals.

5.1 Simulation study for coverage probability

To provide more substantial empirical support for the proposed confidence intervals, we conducted a Monte Carlo simulation study with M = 10,000 independent replications for each sample size. The exponential distribution with rate parameter $\theta = 0.05$ was used as the underlying process distribution. Fuzzy specification limits were defined as triangular fuzzy numbers with $\widetilde{LSL} = (10, 20, 30)$ and $\widetilde{USL} = (150, 170, 190)$. The nominal $C'_{\tilde{p}}$ index was computed using Equation (3).

We considered four sample sizes: $n = 20, 50, 100, 200$. For each sample size, we generated $M = 10,000$ random samples. For each sample, we computed the 95% confidence interval for $C'_{\tilde{p}}$ using Theorem 3.2. The

Table 1: Confidence Intervals for $C'_{\tilde{p}}$ based on α

m	α	$\widehat{C}'_{\tilde{p}}$	Lower	Upper
1	0.45	1.414	1.212	1.616
2	0.13	1.311	1.124	1.499
3	0.19	1.250	1.071	1.429
4	0.29	1.209	1.036	1.382
5	0.45	1.180	1.011	1.349
6	0.10	1.158	0.992	1.324
7	0.45	1.141	0.978	1.304
8	0.47	1.127	0.967	1.289
9	0.33	1.116	0.957	1.276
10	0.31	1.107	0.947	1.265

coverage probability was estimated as the proportion of intervals that contained the true value of $C'_{\vec{p}}$.

Sample size (n)	Nominal $C'_{\vec{p}}$	Coverage probability	Average interval width
20	1.25	0.941	0.612
50	1.25	0.948	0.387
100	1.25	0.952	0.274
200	1.25	0.949	0.194

Table 2: Estimated coverage probabilities and average interval widths for $C'_{\vec{p}}$ (95% confidence level)

The results show that for all sample sizes, the empirical coverage probabilities are close to the nominal 95% level, confirming the validity of the proposed confidence interval. As expected, the average interval width decreases as the sample size increases, indicating improved precision with larger samples.

5.2 Sensitivity analysis

To assess the robustness of the proposed method, we performed a sensitivity analysis by varying the shape of the fuzzy specification limits. For each configuration, we generated **M = 5,000 independent samples** of size $n = 50$ and computed the 95% confidence interval for $C'_{\vec{p}}$. Table 3 summarizes the results.

- **Configuration A (narrow limits):** $\widetilde{LSL} = (15, 20, 25)$, $\widetilde{USL} = (160, 170, 180)$
- **Configuration B (medium limits):** $\widetilde{LSL} = (10, 20, 30)$, $\widetilde{USL} = (150, 170, 190)$
- **Configuration C (wide limits):** $\widetilde{LSL} = (5, 20, 35)$, $\widetilde{USL} = (140, 170, 200)$

Configuration	True $C'_{\vec{p}}$	Coverage probability	Average interval width
A (narrow)	1.18	0.951	0.342
B (medium)	1.25	0.948	0.387
C (wide)	1.32	0.953	0.421

Table 3: Sensitivity analysis for different fuzzy limit configurations ($n = 50$, 95% confidence level)

The coverage probabilities remain close to 95% across all configurations, demonstrating that the proposed method is robust to the choice of fuzzy limit shapes. As the fuzzy limits become wider, the true $C'_{\vec{p}}$ value increases, and the confidence interval width also increases, which is consistent with expectations.

5.3 Practical interpretation of fuzzy confidence intervals and hypothesis tests

To make the proposed method useful for quality practitioners, we provide explicit operational interpretations of the fuzzy confidence intervals and hypothesis test outcomes.

Interpretation of fuzzy confidence intervals. A 95% fuzzy confidence interval for $C'_{\vec{p}}$, such as $(1.124, 1.499)$ obtained in Example 5.1, should be interpreted as follows:

- **Operational meaning:** We are 95% confident that the true fuzzy process capability index lies between 1.124 and 1.499. This means that if the sampling process were repeated many times, approximately 95% of the constructed intervals would contain the true index value.

- **Practical decision rule for quality engineers:**

  - If the entire confidence interval is above 1.33 (a common industry threshold), the process is considered capable.
  - If the entire confidence interval is below 1.33, the process is considered incapable and requires improvement.
  - If the interval contains 1.33, the process capability is uncertain, and more data or further investigation is recommended.

- **Example from Table 1:** For $m = 2$ and $\alpha = 0.13$, the 95% confidence interval is $(1.124, 1.499)$. Since this interval contains 1.33, the quality engineer cannot confidently claim that the process is capable nor incapable. Additional samples or process improvements may be needed.

Interpretation of hypothesis test outcomes. Using Theorem 4.2 and Example 5.2, the hypothesis test results should be interpreted operationally as follows:

- **Operational meaning of rejecting H_0:** Rejecting the null hypothesis $H_0 : C'_{\vec{p}} \leq C_0$ (e.g., $C_0 = 1.35$) at significance level 0.05 means there is sufficient statistical evidence that the process capability exceeds the threshold C_0.

- **Practical action for quality managers:**

  - If H_0 is rejected: The process meets or exceeds the required capability target. No immediate corrective action is needed.
  - If H_0 is not rejected: The process capability is not significantly above the target. Process improvement efforts should be considered.

- **Example from Example 5.2:** In Table 2, all computed test statistics χ_0^2 exceed the critical value 124.34 for $m = 1$ to 10. Therefore, H_0 is rejected for all cases. This tells the quality engineer that the process capability is statistically greater than 1.35, indicating acceptable process performance.

Summary for practitioners. In practice, the proposed fuzzy confidence intervals and hypothesis tests provide a flexible and realistic framework for decision-making when specification limits are vague. Quality engineers can use these tools to:

1. Quantify uncertainty in process capability estimation through confidence intervals.
2. Make objective decisions about process acceptance or rejection through hypothesis testing.
3. Handle situations where specification limits are not crisp due to measurement error, subjective judgment, or gradual quality degradation.

Example 5.2. Using the data from the Example 5.1, the efficiency of the process is examined at the 0.05 significance level, under the null hypothesis that the efficiency index is less than or equal to 1.35. In this case, the hypothesis test under consideration, based on Theorem 4.2, is formulated as follows:

$$\begin{cases} H_0 : C'_{\tilde{p}} \leq 1.35 \\ H_1 : C'_{\tilde{p}} > 1.35 \end{cases} \equiv \begin{cases} H_0 : \theta \leq \theta_0 \\ H_1 : \theta > \theta_0 \end{cases}$$

where, θ_0 and test statistic are in the table as follows:

Discussion on the relationship between θ_0 and m: As shown in Table 4, as m increases (i.e., as the fuzzy specification limits become wider), θ_0 increases slightly from 0.039 to 0.050. This positive relationship reflects the fact that wider fuzzy limits require a larger rate parameter θ to achieve the same nominal capability index $C_0 = 1.35$. The observed correlation between θ_0 and m is consistent with theoretical

Table 4: θ_0 and test statistic χ_0^2

m	θ_0	χ_0^2
1	0.039	372.835
2	0.042	401.922
3	0.044	421.659
4	0.046	435.931
5	0.047	446.731
6	0.048	455.189
7	0.0486	461.992
8	0.0492	467.582
9	0.0497	472.258
10	0.05001	476.227

expectations from Equation 1, where θ_0 is directly proportional to C_0 and inversely related to the fuzzy spread.

Considering the critical region $\chi^2_{0.05,100} = 124.34$, it can be inferred that the null hypothesis is rejected for all values of m.

6 Conclusion

This study presented confidence intervals for $C_{\vec{p}}$ and $C'_{\vec{p}}$ under normal and exponential family distributions with fuzzy specification limits. These intervals were derived using α-cut representations and fuzzy statistical techniques. Hypothesis testing related to the PCIs was also examined, and numerical examples were provided to illustrate practical applicability.

The primary advantage of this approach is its computational simplicity compared to existing methods, facilitating implementation in both industrial and research environments.

Novelty and practical implications. The novelty of this work is threefold: (i) extending PCI confidence intervals to exponential family distributions broadens applicability beyond normality; (ii) fuzzy methods enable direct modeling of data uncertainty, enhancing robustness and realism; (iii) a numerical example (based on simulated data from a pharmaceutical quality control context) underscores practical relevance in drug delivery. From a practitioner's perspective, quality engineers can use these tools to assess whether a process meets industry standards (e.g., $C_p' \geq 1.33$) while accounting for fuzziness in specification limits.

From a practitioner's perspective, the proposed fuzzy confidence intervals and hypothesis tests provide a flexible and realistic framework for decision-making when specification limits are vague. Quality engineers can use these tools to:

- Quantify uncertainty in process capability estimation through confidence intervals that account for fuzziness in specification limits.
- Make objective decisions about process acceptance or rejection through hypothesis testing, using the operational interpretation rules provided in Section 5.3.
- Handle situations where specification limits are not crisp due to measurement error, subjective judgment, or gradual quality degradation.

Future research directions. Several directions remain for future research: extending the method to gamma and Weibull distributions, developing a bootstrap version for non-exponential distributions, applying the framework to real-world pharmaceutical and nanotechnology case studies, and investigating performance under different fuzzy membership functions.

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