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# Application of a fuzzy mixed sampling plan for Sterile drug vial testing in the pharmaceutical industry

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**Abstract**:

Testing every unit is often not an option when inspection is destructive or expensive, yet classical acceptance sampling plans struggle to represent the uncertainty that naturally surrounds a defect rate in such settings. This paper develops a fuzzy mixed sampling plan indexed through the fuzzy Acceptable Quality Level (AQL) and fuzzy Limiting Quality Level (LQL), pairing fuzzy variable sampling at the first stage with a Fuzzy Chain Sampling Plan (FChSP) at the second. The fraction defective is treated as an interval-valued fuzzy number, and the overall acceptance probability is derived analytically and split between the two stages. A further contribution places both design procedures inside a single minimax risk-constrained optimization problem: the AQL-based design turns out to be the exact minimax-optimal solution, while the LQL-based design deliberately settles for a smaller, cheaper sample size, giving up a quantifiable amount of worst-case consumer protection in exchange for less destructive testing. Design tables cover chain indices $i = 1$ to 5 and are demonstrated on sterile drug vial inspection. The AQL-based illustration ($p_1$ = [0.009, 0.010], pa1 = 0.95,$i = 3$) yields parameters ($n_1$, $n_2$, k, i) = (4, 26, 2.484, 3), while the LQL-based illustration ($p_2$ = [0.03, 0.04], pa2 = 0.05, $i = 1$) yields (4, 106, 0.8447, 1). As $p_1$ moves from [0.001, 0.002] up to [0.009, 0.010], the acceptance constant $k$ drops from [3.035, 3.283] to [2.484, 2.558] and the second-stage sample size $n_2$ shrinks from [191, 383] to [38, 43], cutting destructive inspection without giving up the specified producer's and consumer's risks. A larger first-stage sample, from [4, 6] to [9, 11], tightens the interval on $k$ by roughly 30%, sharpening precision, and the chain index itself has only a marginal effect on the results. Taken together, the findings point to a framework that is both mathematically well-founded and practical for destructive quality control in pharmaceutical manufacturing.

***Keywords**:* Fuzzy chain sampling plan, mixed sampling plan, fuzzy acceptance sampling, acceptable quality level, limiting quality level, operating characteristic curve, pharmaceutical quality control.

## 1. Introduction

In modern manufacturing industries, particularly where testing is expensive or destructive, ensuring product quality while minimizing inspection cost remains a significant challenge. Traditional acceptance sampling plans perform well when process conditions are clearly defined. However, they become less effective in situations involving uncertainty or when the exact proportion of defective items cannot be determined precisely. In such cases, conventional probability-based sampling methods are inadequate for representing the uncertainty inherent in real-world production processes. To address this limitation, fuzzy set theory has increasingly been adopted as an effective tool for modelling uncertainty in product quality. The Fuzzy Chain Sampling Plan (FChSP) provides a flexible framework by integrating fuzzy logic with chain sampling concepts. This approach improves the reliability of acceptance decisions because the acceptance of the current lot depends on the quality of previously inspected lots, thereby providing better monitoring of production quality over time.

This paper proposes a fuzzy mixed sampling plan that integrates a fuzzy variable sampling procedure in the first stage with a Fuzzy Chain Sampling Plan (FChSP) as the second-stage attribute inspection procedure. The proposed plan is indexed through the fuzzy Acceptable Quality Level (AQL) and the fuzzy Limiting Quality Level (LQL). The methodology allocates the required acceptance probability between the two inspection stages while satisfying the specified producer's and consumer's risks. The first stage employs fuzzy variable sampling based on known process parameters, whereas the second stage performs fuzzy attribute inspection using a predefined chain index $i$ , thereby incorporating lot-to-lot quality information into the acceptance decision.

The proposed methodology is particularly suitable for pharmaceutical manufacturing, where the quality inspection of sterile drug vials often involves destructive tests such as sterility and chemical analysis. Since the tested vials cannot be reused and the true defect level is uncertain because of process variability, conventional sampling plans are difficult to apply effectively. The proposed fuzzy mixed sampling plan addresses this challenge by representing the fraction defective using interval-valued fuzzy parameters, thereby reducing destructive inspection while maintaining reliable acceptance decisions.

The significance of this work lies in providing a practical acceptance sampling methodology for destructive quality inspection under uncertain production environments. By integrating fuzzy variable sampling with fuzzy chain sampling, the proposed approach reduces inspection effort while preserving reliable lot acceptance and rejection decisions. Consequently, the methodology is particularly useful for pharmaceutical quality assurance, where both regulatory compliance and inspection efficiency are essential.

In this study, fuzzy quality parameters are represented using interval-valued fuzzy numbers, and the analysis is carried out using their **0-cut**, which captures the complete range of uncertainty and provides a conservative sampling design suitable for costly or destructive products. By incorporating fuzzy probability concepts and Operating Characteristic (OC) analysis, the proposed methodology provides a practical framework for determining fuzzy acceptance constants and second-stage sample sizes for various chain indices.

The main contributions of this study are summarized as follows

- A fuzzy mixed sampling plan indexed through fuzzy AQL and fuzzy LQL is proposed for destructive quality inspection.
- A Fuzzy Chain Sampling Plan (FChSP) is incorporated as the second-stage attribute inspection procedure within the mixed sampling framework.
- Interval-valued fuzzy numbers are employed to model uncertainty in the fraction defective while preserving the classical mixed sampling framework.
- Design tables for the fuzzy acceptance constant and fuzzy second-stage sample size are developed for different first-stage sample sizes and chain indices.
- The applicability of the proposed methodology is demonstrated through the quality inspection of sterile drug vials in pharmaceutical manufacturing.

The remainder of this paper is organized as follows. Section II reviews the existing literature related to fuzzy acceptance sampling and fuzzy chain sampling plans. Section III presents the proposed fuzzy mixed sampling plan. Section III.1 lists the symbols used in the proposed plan. Section III.2 formulates the plan with interval-valued fuzzy parameters and includes the lot disposition algorithm, performance measures, and the fuzzy Operating Characteristic (FOC) band. Section III.3 develops the fuzzy mixed sampling plan indexed through the Acceptable Quality Level (AQL) using the Fuzzy Chain Sampling Plan (FChSP) as the second-stage attribute inspection procedure, together with a numerical illustration. Section III.4 presents the design of the fuzzy mixed sampling plan indexed through the Limiting Quality Level (LQL), together with a numerical illustration. Section III.5 formulates both design procedures as instances of a common minimax risk-constrained optimization problem,

establishing the AQL-based design as an exact minimax-optimal solution and the LQL-based design as a cost-driven relaxation of it. Section IV presents the results and discussion, including the limitations and practical challenges of the proposed approach. Finally, Section V concludes the paper by summarizing the major findings and suggesting directions for future research.

## 2. Literature Review

Mixed acceptance sampling plans have been developed to combine the advantages of variables and attribute inspection while reducing overall inspection effort. An early mixed sampling procedure incorporated variables inspection in the first stage and chain sampling in the second stage, demonstrating improved operating characteristics and better discrimination between acceptable and non-acceptable lots than conventional single-stage sampling plans (Suresh & Devaarul, 2002). This work established the theoretical foundation for subsequent developments in mixed sampling methodologies, and it is retained here, despite predating the most recent fifteen-year window, because the mixed sampling algorithm proposed in this paper is a direct fuzzy extension of this classical framework.The incorporation of fuzzy set theory into acceptance sampling has significantly enhanced the ability of sampling plans to handle uncertainty arising from imprecise quality characteristics. Initial studies introduced fuzzy probability theory into chain sampling by representing sampling parameters as fuzzy numbers, resulting in more flexible operating characteristic curves than those obtained using classical probability models (Jamkhaneh & Gildeh, 2011). Fuzzy acceptance sampling plans were subsequently developed by expressing the fraction defective as a fuzzy parameter, thereby improving the realism of acceptance decisions under uncertain manufacturing environments (Sadeghpour Gildeh et al., 2011). Further investigations on fuzzy acceptance sampling characteristic curves demonstrated that fuzzy modelling effectively represents uncertainty while maintaining desirable producer's and consumer's risks (Turanoğlu et al., 2012).

Research during the following years concentrated on improving chain sampling procedures. Relational chain sampling plans were introduced by utilizing information from previous lots to improve inspection efficiency while reducing sampling costs (Deva Arul & Moses, 2017). Chain sampling plans indexed through acceptable quality level (AQL) and limiting quality level (LQL) were subsequently proposed to provide better discrimination between acceptable and rejected lots (Raju & Vidya, 2017). In addition, modified chain sampling plans based on variables inspection and process capability indices were developed to improve decision-making when process parameters were unknown, thereby extending the applicability of chain sampling to practical industrial situations (Luca, 2018; Balamurali & Usha, 2017). The application of chain sampling concepts was further expanded to destructive and costly inspection. Two-sided modified complete chain sampling plans were developed for small sample situations, providing improved producer's and consumer's protection without substantially increasing inspection effort (Milky Mathew & Rajeswari, 2019). Relational chain sampling plans were also extended using average outgoing quality limit (AOQL) and minimum tangent criteria to improve inspection performance for non-destructive products (Vijila & Grace, 2019). To address uncertainty caused by measurement errors, neutrosophic statistics was introduced into acceptance sampling by defining neutrosophic sample size and acceptance number parameters. Although the proposed approach offered greater flexibility than conventional sampling plans, its application remained limited to single acceptance sampling procedures (Aslam, 2019). Further developments focused on enhancing the efficiency of chain sampling techniques. Two-sided relational chain sampling plans utilized information from both preceding and succeeding lots to improve operating characteristics and reduce inspection costs (Deva Arul & Jothimani, 2020). Bayesian two-sided group chain sampling plans were subsequently proposed for beta-binomial models, achieving reduced sample sizes while maintaining specified producer's and consumer's risks over different quality regions (Hafeez & Aziz, 2022).

More recent studies have concentrated on integrating fuzzy concepts with advanced chain sampling procedures. A fuzzy two-stage chain sampling plan represented the fraction defective, sample size, and acceptance number using triangular fuzzy numbers, resulting in wider and more flexible operating characteristic regions than classical chain sampling plans (Sangeetha & Karunya, 2022). Similarly, two-sided complete chain sampling plans employing trapezoidal fuzzy numbers reduced both producer's and consumer's risks while maintaining consistent product quality (Kavipriya & Sudamani Ramaswamy, 2022). Fuzzy acceptance sampling plans based on the transmuted Weibull distribution further demonstrated that fuzzy operating characteristic (FOC) curves provide more reliable acceptance decisions under uncertain production environments (Khan et al., 2022). Recent investigations have expanded fuzzy acceptance sampling in several directions. Comprehensive review studies emphasized the increasing importance of fuzzy logic in statistical quality control and recommended extending fuzzy methodologies to more advanced acceptance sampling systems (Uma & Ramya, 2023; Bhattacharyya, 2023). Acceptance sampling plans based on the generalized Poisson distribution treated the fraction defective as a fuzzy parameter, thereby improving flexibility and modelling capability under uncertainty (Ramya & Merlinvinola, 2023). Generalized Fuzzy Multiple Deferred State (GFMDS) sampling plans further reduced inspection effort while maintaining satisfactory protection for both producers and consumers through fuzzy decision-making (Thomas & Kumar, 2023).

Overall, the existing literature demonstrates substantial progress in mixed sampling, fuzzy acceptance sampling, chain sampling, relational chain sampling, Bayesian approaches, and neutrosophic statistics. Nevertheless, these developments have largely been investigated independently. Classical mixed sampling plans have not been integrated with fuzzy interval modelling in both variables and attribute inspection stages, particularly when the second stage employs a fuzzy chain sampling plan (FChSP) for destructive products. Consequently, a comprehensive fuzzy mixed sampling framework that simultaneously addresses uncertainty in both inspection stages and improves decision-making for destructive testing remains unavailable. This research is intended to bridge this gap by developing a fuzzy mixed sampling plan based on fuzzy interval variables inspection in the first stage and a fuzzy chain sampling plan (FChSP) in the second stage.

## 3. Proposed methodology

### 3.1. List of symbols used in the fuzzy mixed sampling plan

**Table 1:** Notations and definitions used in the proposed fuzzy mixed sampling plan.

| Symbol | Interpretations |
|---|---|
| N | Lot size |
| $i$ | Chain index represents the dependency on previous lot decisions in chain sampling plan |
| U | Upper specification limit for the quality characteristic |
| $\sigma$ | Known process Standard deviation of the quality characteristic |
| A | Acceptance limit computed for the first stage variable inspection |
| $\bar{X}$ | Sample mean of the variable inspection |
| D | Number of defectives in the second stage attribute inspection |
| $\tilde{p}$ | Interval valued fuzzy fraction defective$[FL(p), UL(p)]$ |
| $p$ | Crisp fraction defective (operational value) |
| $\tilde{p}_1$ | Fuzzy representation of the acceptable quality level |
| $\tilde{p}_2$ | Fuzzy representation of the Limiting quality level |
| $\widetilde{n_1}$ | Fuzzy Sample size for the first stage (variable inspection), $[FL(n_1), UL(n_1)]$ |
| $\widetilde{n_2}$ | Fuzzy interval of the sample size for the second stage (attribute inspection) ,$[FL(n_2), UL(n_2)]$ |
| $n_1$ | Operational first stage sample size |
| $n_2$ | Operational second stage sample size |
| $\tilde{k}$ | Fuzzy variable factor), $[FL(k), UL(k)]$ |
| $k$ | Operational variable factor |
| $p_a$ | Overall acceptance probability of the fuzzy mixed sampling plan |
| $p_a^L$ | Lower Acceptance probability |
| $p_a^U$ | Upper Acceptance probability |
| $p_{a1}$ | Acceptance Probability at the AQL point |
| $p_{a2}$ | Acceptance Probability at the LQL point |
| $p_{a1}^{'}$ | Acceptance Probability designated for the first stage of inspection (variable inspection) |
| $p_{a1}^{''}$ | Acceptance Probability designated for the second stage of inspection (attribute inspection) after adjusting for the first stage |
| $p_{a2}^{'}$ | Acceptance Probability designated for the first stage of inspection (variable inspection) at LQL level |
| $p_{a2}^{''}$ | Acceptance Probability designated for the second stage of inspection (attribute inspection) after adjusting for the first stage at LQL level |
| $\widetilde{p_V}\ (\tilde{p})$ | Fuzzy first stage acceptance probability |
| $\tilde{p}_0$ | Fuzzy probability that the second-stage attribute sample contains zero defectives, D = 0 |
| $\tilde{q}_1$ | Fuzzy probability that the second-stage attribute sample contains exactly one defective, D = 1 |
| Z(.) | Standard normal deviate (z value) corresponding to the given probability |
| FL(.), UL(.) | Lower and upper bound operators applied to a fuzzy interval, e.g. FL ($\widetilde{n_2}$), UL ($\widetilde{n_2}$); used in the same lower/upper sense as the $p_a^L$, $p_a^U$ notation and the bracket form $\widetilde{p_a}(\tilde{p})$ used for the acceptance probability elsewhere in the text. |

Table 1 summarizes the symbols and their interpretations used to formulate the fuzzy mixed sampling plan, including lot size, inspection sample sizes, quality limits, and fuzzy fraction-defective intervals. It also defines the acceptance probabilities, statistical parameters, and lower and upper bound operators required for evaluating the sampling plan's performance.

### 3.2. Formulation of a Mixed Sampling Plan with Fuzzy Parameters

The proposed fuzzy mixed sampling plan follows a sequential two-stage inspection procedure that combines variable inspection with chain attribute inspection under interval-valued fuzzy uncertainty. The overall structure of the algorithm is adapted from the classical mixed sampling plan proposed by Suresh & Devaarul, (2002), while the variable and attribute inspection stages are reformulated using interval-valued fuzzy parameters to account for uncertainty in the sample size, acceptance constant, and fraction defective. The algorithm provides a systematic procedure for lot disposition based on fuzzy operating characteristic (FOC) design requirements and fuzzy chain sampling principles (Suresh & Devaarul, 2002; Jamkhaneh & Gildeh, 2011).

The plan is developed to meet both the limiting quality level and the acceptable quality level criteria within a fuzzy uncertainty condition. The formulation of this scheme is based on a single upper specification U and a known standard deviation $\sigma$.By analogy with a classical approach, the fuzzy based plan is characterised by the factors $\widetilde{n_1}, \widetilde{n_2}, \tilde{k}, and\ i$ were

$\widetilde{n_1}$: $[FL(n_1), UL(n_1)]$:fuzzy first stage sample size used for variable inspection

$\widetilde{n_2} =:\ [FL(n_2), UL(n_2)]$:the fuzzy interval corresponding to the second-stage attribute inspection sample

$\tilde{k}$ : $[FL(k), UL(k)]$:the fuzzy variable that makes the lot accepted if (Equation 1)

$$\bar{X} \leq \tilde{A} = U - \tilde{k}\sigma \tag{1}$$

otherwise, the lot proceeds to the second stage

$i$ : chain index denoting the dependency on the results of the $i$ immediately preceding lots

An interval valued fuzzy approach is employed, and the lower bounds of the fuzzy parameters are adopted for operational calculations to obtain a conservative mixed sampling.

#### 3.2.1.
#### Algorithm for Lot disposition of the proposed mixed sampling plan with fuzzy parameters

The algorithm for implementing the proposed fuzzy mixed sampling plan is summarized below.

**Step 1**: Determine the four parameters $\widetilde{n_1}, \widetilde{n_2}, \tilde{k}, and\ i$ using the fuzzy operating characteristic (FOC) and fuzzy average sample number (FASN) or from a given design specification such as AQL and LQL. The parameter estimation follows the mixed sampling framework of Suresh & Devaarul, (2002), extended here to interval-valued fuzzy parameters.

**Step 2**: The fuzzy parameters are represented as interval-valued fuzzy numbers

$$\widetilde{n_1}: [FL(n_1), UL(n_1)] \qquad \widetilde{n_2} =: [FL(n_2), UL(n_2)] \qquad \tilde{k} : [FL(k), UL(k)]$$

For operational implementation the crisp values are selected as

$$n_1 = FL(n_1) \ \ , \ \ n_2 = FL(n_2)\ , \quad k = FL(k)$$

FL(.) denotes the lower bounds of the fuzzy interval associated with the respective parameter.

**Step3**: Draw a variable sample of size $n_1 = FL(n_1)$ from the lot under inspection and compute the sample mean $\bar{X}$. The lot is accepted at the first stage if $\bar{X} \leq A = U - k\sigma$, where k $= FL(k)$;otherwise, the lot is proceeded to the second stage attribute inspection.

**Step 4**: For the second stage determine the fuzzy attribute sample size $\widetilde{n_2} =: [FL(n_2), UL(n_2)]$ using the chain sampling acceptance probability relation (Equation 2)

$$e^{-n_2 p} + n_2 p\, e^{-n_2 p(i+1)} \ = \ p_a^{''},\ p \in [FL(p), UL(p)] \tag{2}$$

Here, $p$ denotes the fraction defective at the acceptable quality level, modelled as an interval valued fuzzy parameter and $p_a^{''}$ represents the fuzzy acceptance probability associated with the attribute stage.

**Step 5**: Inspect the second-stage sample and record the count of defective pieces $D$.The decision rules are as follows

(i) If $D = 0$,the lot shall be considered acceptable
(ii) If $D > 1$,the lot shall be rejected
(iii) If $D = 1$, the present lot is accepted only when the preceding $i$ lots were accepted; otherwise, it is rejected.

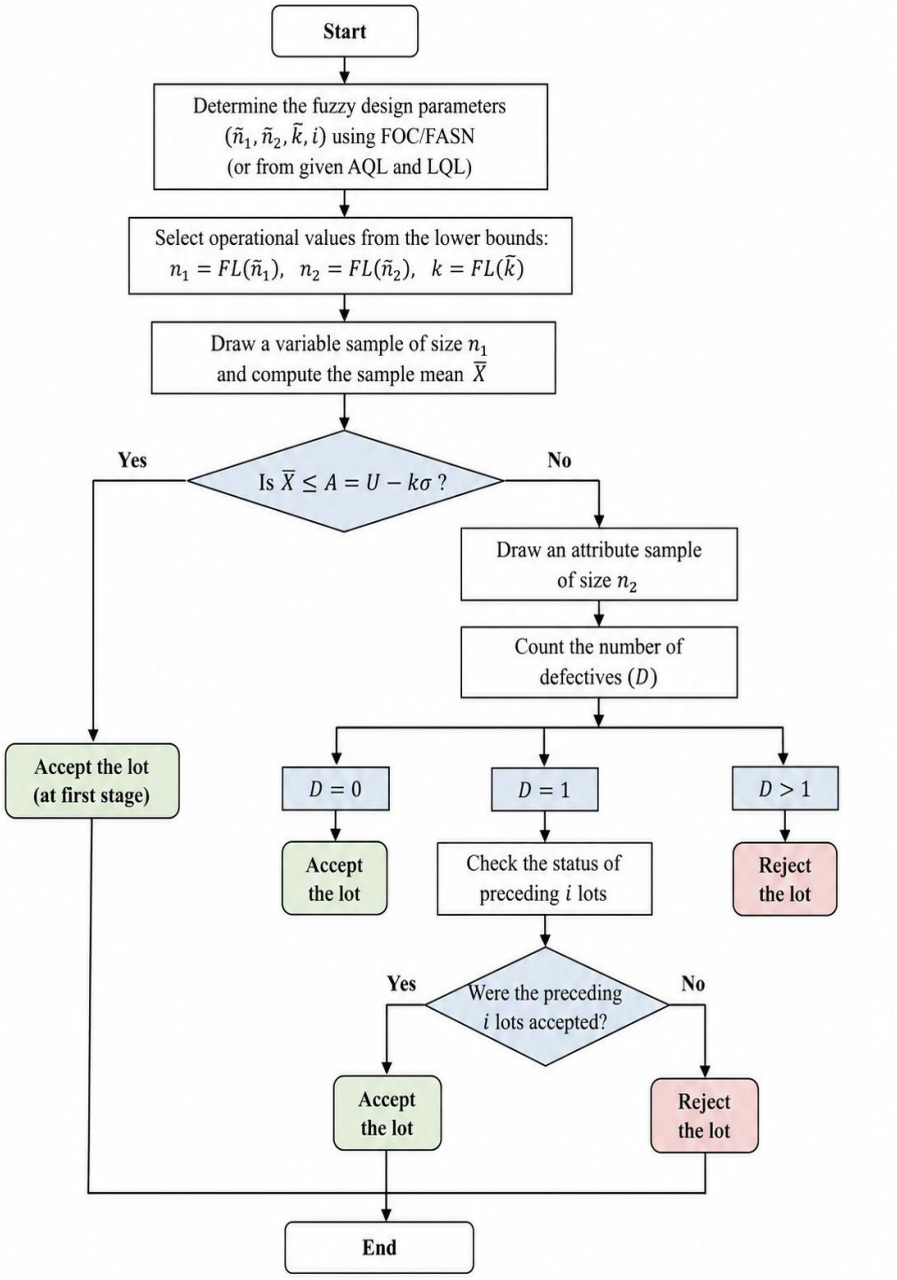


**Figure 1:** Flowchart of the proposed fuzzy mixed sampling plan inspection procedure.

Figure 1 illustrates the sequential inspection process, beginning with fuzzy design parameter selection and first-stage variable inspection using the sample mean. If the lot is not accepted at the first stage, a second-stage attribute inspection evaluates the number of defectives and the acceptance status of preceding lots to determine final lot acceptance or rejection.

### 3.2.2. Measures of fuzzy mixed sampling plan

The performance of the mixed sampling plan framework incorporating fuzzy chain attribute inspection can be evaluated using the following fuzzy parameters. These measures incorporate the effect of fuzziness in both variable and attribute inspection stages.

**Theorem 1: Fuzzy probability of acceptance**

For the suggested mixed sampling strategy in III.2.1, the fuzzy acceptance probability is given by

$$\widetilde{p_a}\,(\tilde{p}) = \widetilde{p_V}\,(\tilde{p}) + \left(1 - \widetilde{p_V}\,(\tilde{p})\right)\,[\widetilde{p_0}\,(\tilde{p}) + \widetilde{q_1}\,(\tilde{p})\,(\widetilde{p_0}\,(\tilde{p}))^i] \quad (3)$$

Where $\widetilde{p_V}\,(\tilde{p}) = \tilde{P}\,(\bar{X} \le A \,/\, \tilde{p})$

$\widetilde{p_0}\,(\tilde{p}) = \tilde{P}\,(D = 0 \,/\, \tilde{p}), \quad \widetilde{q_1}\,(\tilde{p}) = \tilde{P}\,(D = 1 \,/\, \tilde{p})$

Here in equation (3), $\widetilde{p_V}\,(\tilde{p})$ represents the likelihood of acceptance in the initial stage (variable inspection) and the bracketed term represents the conditional likelihood of acceptance at the second stage (attribute inspection), given rejection at the first stage.

**Proof:**

Let $V = \{\bar{X} \le A\}$ denote the event that the lot is accepted at the first stage and let C denote the event that the lot is accepted at the second stage. The overall lot acceptance event is

$\mathcal{A} = V \cup (V^c \cap C)$ i.e, the lot is accepted either at stage 1, or it fails stage 1 and is then accepted at stage 2

Since $V \;\; and \;\; (V^c \cap C)$ are two disjoint events, by additivity of probability (Equation 4),

$$P(\mathcal{A}) = P(V) + (V^c \cap C)$$

Using the definition of conditional probability $(V^c \cap C) = P(V^c)\,P(C/V^c)$

$$\text{Hence } P(\mathcal{A}) = P(V) + P(V^c)\,P(C/V^c) \;\; = \;\; P(V) + \left(1 - P(V)\right)P(C/V^c) \quad (4)$$

According to the mixed sampling plan's operating process, stage 2 is performed only when $V^c$ occurs, and the attribute stage decision depends only on the attribute sampling outcomes and the chain rule. Therefore, the conditional acceptance probability at stage 2 can be written as the attribute stage acceptance probability $P(C)$ and (4) becomes (Equation 5),

$$P(\mathcal{A}) = P(V) + \left(1 - P(V)\right)P(C) \quad (5)$$

Now evaluate $P(C)$ using chain rule.Let D be the number of flaws in the size $n_2$ second stage attribute sample . Under the stated chain acceptance rule with index $i$,the lot is accepted at stage 2 if (i) D=0 or,

(ii) D=1 and each of the immediately preceding lots $i$ had D=0 at the attribute stage

Let $p_0 = P(D = 0)$ and $q_1 = P(D = 1)$. Also let B be the event that the previous $i$ lots had D=0 at the attribute stage. Then $C = \{D = 0\} \cup (\{D = 1\} \cap B)$ and the two parts are disjoint. Hence (Equation 6)

$$P(C) = P(D = 0) + P(D = 1 \cap B) \quad (6)$$

Assuming the attribute stage outcomes across successive lots are independent (Equation 7)

$$P(D = 1 \cap B) = P(D = 1)P(B) = q_1\,[P(D = 0)]^i = q_1\,p_0^i \quad (7)$$

Substituting (7) in (6) gives $P(C) = p_0 + q_1\,p_0^i$

Substituting this expression into the total probability relation (5) gives

$P(\mathcal{A}) = P(V) + (1 - P(V))\,[p_0 + q_1\,p_0^i]$. Replacing $P(V)$ by $p_v\,(p) = P\,(\bar{X} \le A \,/\, \text{p})$,and extending the probabilities to interval valued fuzzy quantities under $\tilde{p}$ gives

$\widetilde{p_a}\,(\tilde{p}) = \widetilde{p_V}\,(\tilde{p}) + \left(1 - \widetilde{p_V}\,(\tilde{p})\right)\,[\widetilde{p_0}\,(\tilde{p}) + \widetilde{q_1}\,(\tilde{p})\,(\widetilde{p_0}\,(\tilde{p}))^i]$. Hence the proof.

**Theorem 2: The fuzzy average sample size**

For the proposed mixed sampling plan the fuzzy average sample size is the mean count of units examined per lot and that can be calculated as follows

$$FASN = \widetilde{n_1} + \widetilde{n_2}[1 - \widetilde{p_V}\,(\tilde{p})] \quad (8)$$

where $\widetilde{p_V}\,(\tilde{p})$ denote the probability of acceptance at the initial stage.

FASN shows how uncertainty in lot quality and inspection decision impacts the expected inspection effort.

Proof:

Let $V = \{\bar{X} \leq A\}$ be the event that the lot is accepted at the first stage. Under the mixed sampling plan, the number of inspected units per lots is $T = \widetilde{n_1} + \widetilde{n_2}\, I(V^c)$ where $I(V^c)$ is the indicator of the event that the lots proceed to the second stage. Taking expectation

$$E(T) = \widetilde{n_1} + \widetilde{n_2}\, I(V^c) = \widetilde{n_1} + \widetilde{n_2}[1 - P(V)]$$

Replacing $P(V)$ by $\widetilde{p_V}\,(\tilde{p})$ under interval valued fuzziness yields equation (8).

**Theorem 3: Fuzzy average total inspection**

For the proposed mixed sampling plan, the fuzzy average total inspection represents the expected total count of units examined per lot, considering both the sampled items and those associated with accepted or rejected lots (Equation 9).

$$FATI = FASN + (N - \widetilde{n_1} - \widetilde{n_2})\big(1 - \widetilde{p_a}\,(\tilde{p})\big) \tag{9}$$

FATI measures the total fuzzy inspection workload, showing how lot rejection probabilities influence total inspection effort.

**Proof**

Let T be the total number of inspected units per lot. Under the plan a variable sample of size $\widetilde{n_1}$ is always inspected. An attribute sample of size $\widetilde{n_2}$ is inspected only if the lot proceeds to stage 2. Thus, the expected sample inspected is $FASN$.If the lot is rejected (event $\mathcal{A}^c$) ,rectification requires inspection of the remaining units in the lot is equal to $(N - \widetilde{n_1} - \widetilde{n_2})$

Hence T= sampled inspection +$(N - \widetilde{n_1} - \widetilde{n_2})\, I(\mathcal{A}^c)$ where $I(\mathcal{A}^c)$ denotes the lot rejection (Equation 10).

Taking the expectation $E(T) = FASN + (N - \widetilde{n_1} - \widetilde{n_2})P(\mathcal{A}^c)$ (10)

Now $P(\mathcal{A}^c) = 1 - P(\mathcal{A}) = 1 - \widetilde{p_a}\,(\tilde{p})$.So equation (10) becomes

$$FATI = FASN + (N - \widetilde{n_1} - \widetilde{n_2})(1 - \widetilde{p_a}\,(\tilde{p}))$$

**Theorem 4: Fuzzy average outgoing quality**

Under the fuzzy mixed sampling plan the fuzzy average outgoing quality indicates the anticipated quality level of lots following inspection and acceptance when fuzziness or uncertainty is involved (Equation 11).

$$FAOQ = \tilde{p} * \widetilde{p_a}\,(\tilde{p}) \tag{11}$$

**Proof**

Average outgoing quality is defined as the expected fraction nonconforming in the outgoing stream after applying the inspection plan. Under a rectifying sampling scheme, accepted lots pass to the outgoing stream without further screening, while rejected lots are screened and corrected.

Let $\mathcal{A}$ denote the event that the lot is accepted. Then the outgoing fraction defective Q for a lot can be written as

$$Q = \begin{cases} \tilde{p}, & if\ \mathcal{A}\ occurs(lot\ accepted) \\ 0 & if\ \mathcal{A}^{\,c}\ occurs(lot\ rejected\ and\ rectified) \end{cases}$$

Therefore, using expectation (Equation 12),

$$E(Q) = \tilde{p} * P(\mathcal{A}) + 0 * P(\mathcal{A}^{\,c}) = \tilde{p} * P(\mathcal{A}) \tag{12}$$

Since $P(\mathcal{A})$=$\widetilde{p_a}\,(\tilde{p})$, by definition of acceptance probability,

$$FAOQ = \tilde{p} * \widetilde{p_a}\,(\tilde{p})$$

**3.2.3. Fuzzy Operating Characteristic band (F.O.C band)**

The fuzzy operating band is constructed by plotting the lower and upper bounds of the probability of acceptance against the fraction defective. To study the OC behaviour of the proposed mixed sampling plan, the parameters are fixed as $n_1 = 5, n_2 = 76, k = 2.822, i = 2$

These values are taken from Table 4 for the fuzzy defect level $\tilde{p} = [0.003, 0.004]$

Using equation (2), the likelihood of probability is calculated for different fuzzy fraction defective intervals from [*0.001,0.002*] to [*0.009,0.010*].For each interval the lower and upper values of the acceptance probability are obtained and plotted to form the fuzzy OC band.

The OC band shows that the likelihood of probability decreases as the fraction defective increases. The small gap between the upper and lower curves indicates that the proposed mixed sampling plan gives stable results under fuzzy conditions.

**Table 2:** Fuzzy OC band values for the proposed mixed sampling plan.

$$\boldsymbol{n_1 = 5, n_2 = 76, k = 2.822, i = 2}$$

| Fuzzy fraction defective $\tilde{p}$, | Lower probability of acceptance $p_a^L$ | Upper probability of acceptance $p_a^U$ |
|---|---|---|
| [0.001,0.002] | 0.9991 | 0.9995 |
| [0.002,0.003] | 0.9980 | 0.9991 |
| [0.003,0.004] | 0.9962 | 0.9980 |
| [0.004,0.005] | 0.9935 | 0.9962 |
| [0.005,0.006] | 0.9900 | 0.9935 |
| [0.006,0.007] | 0.9855 | 0.9900 |
| [0.007,0.008] | 0.9800 | 0.9855 |
| [0.008,0.009] | 0.9735 | 0.9800 |
| [0.009,0.010] | 0.9660 | 0.9735 |

For the Second case:

To examine the effect of first stage sample size, another plan is considered

With $n_1 = 10, n_2 = 76, k = 2.822, i = 2$

The corresponding fuzzy OC band values are given in table 3.

**Table 3:** Fuzzy OC band values for the proposed mixed sampling plan.

$$\boldsymbol{n_1 = 10, n_2 = 76, k = 2.822, i = 2}$$

| Fuzzy Fraction Defective $\tilde{p}$, | Lower Probability of Acceptance $p_a^L$ | Upper Probability of Acceptance $p_a^U$ |
|---|---|---|
| [0.001,0.002] | 0.9993 | 0.9997 |
| [0.002,0.003] | 0.9984 | 0.9993 |
| [0.003,0.004] | 0.9970 | 0.9984 |
| [0.004,0.005] | 0.9948 | 0.9970 |
| [0.005,0.006] | 0.9918 | 0.9948 |
| [0.006,0.007] | 0.9880 | 0.9918 |
| [0.007,0.008] | 0.9832 | 0.9880 |
| [0.008,0.009] | 0.9775 | 0.9832 |
| [0.009,0.010] | 0.9708 | 0.9775 |

Table 2 shows the fuzzy OC band obtained for $n_1 = 5$, while table 3 shows the corresponding band for $n_1 = 10$. Comparing the two indicates that increasing the first stage sample size slightly increases the probability of acceptance for good quality lots and results in a narrower OC band. This indicates improved discrimination between acceptable and non-acceptable quality levels.

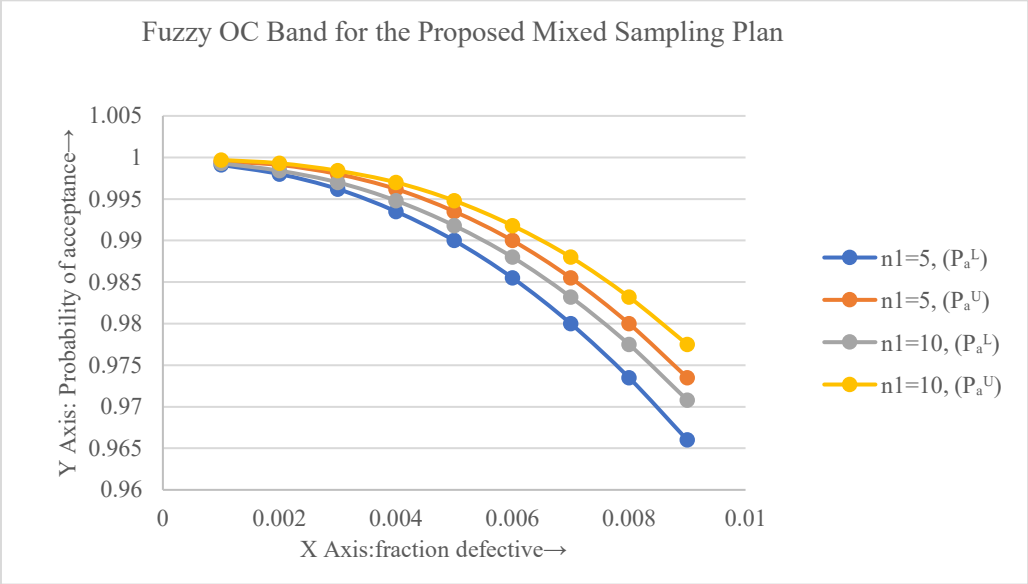


**Figure 2:** Fuzzy operating characteristic (OC) curves for the proposed mixed sampling plan.

Figure 2 illustrates the relationship between the fraction defective and the probability of acceptance for different sample sizes ($n_1 = 5$, $n_2 = 10$) under fuzzy conditions. As the fraction defective increases, the probability of acceptance decreases, indicating the effectiveness of the proposed mixed sampling plan in distinguishing between good- and poor-quality lots.

The OC band becomes narrower as the first-stage sample size increases from $n_1 = 5$ to $n_1 = 10$

This indicates that the proposed mixed sampling plan provides improved precision and better discrimination between acceptable and poor-quality lots for larger first stage sample sizes.

### 3.3. Design of a mixed sampling plan indexed through AQL using fuzzy chain sampling as the attribute plan

The process for developing a mixed sampling plan that employs a fuzzy chain sampling plan as it's attribute plan, to satisfy $\widetilde{p_1}$, $p_{a1}$, $i$ and determine the fuzzy initial stage sample size $\widetilde{n_1}$, on the OC curve is as follows

Suppose that the composite sampling plan operates independently

1)Divide the overall probability of acceptance, and assign a portion of it to the initial stage. Let it be $p'_{a1}$

2) Select the sample count for the initial stage and denote it as $\widetilde{n_1}$

3)Compute the acceptance limit using the formula $A = U - \left[Z(\widetilde{p_1}) + \frac{Z(p'_{a1})}{\sqrt{n_1}}\right]\sigma$ (13)

4)Calculate the probability of acceptance $p''_{a1}$, allocated to the second stage attribute plan, using the relation

$$p''_{a1} = \frac{p_{a1} - p'_{a1}}{1 - p'_{a1}} \quad (14)$$

5)Identify the suitable sample size $\widetilde{n_2}$ for the second stage defined as $\widetilde{n_2} = [FL(n_2), UL(n_2)]$ for a given chain index $i$ using the relation (Equation 15)

$$e^{-n_2 p} + n_2 p\, e^{-n_2 p(i+1)} = p''_{a1} \quad \text{where } p \epsilon \tilde{p}[\alpha] \quad (15)$$

**Table 4:** Values of fuzzy second stage sample size $(\widetilde{n_2})$ and fuzzy variable factor $\tilde{k}$ for different chain indices (AQL based design).

| $\widetilde{p_1}$ | Values of $\widetilde{n_2} = [FL(n_2), UL(n_2)]$ | | | | | | Variable factor $\tilde{k}$ | |
|---|---|---|---|---|---|---|---|---|
| | $i = 1$ | $i = 2$ | $i = 3$ | $i = 4$ | $i = 5$ | | $\widetilde{n_1} = [4, 6]$ | $\widetilde{n_1} = [9, 11]$ |
| [0.001,0.002] | [191,383] | [152,304] | [132,264] | [119,239] | [111,221] | | [3.035,3.283] | [2.994,3.219] |
| [0.002,0.003] | [128,191] | [101,152] | [88,132] | [80,119] | [74,111] | | [2.905,3.071] | [2.864,3.006] |
| [0.003,0.004] | [96,128] | [76,101] | [66,88] | [60,80] | [55,74] | | [2.809,2.940] | [2.768,2.876] |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| [0.004,0.005] | [77,96] | [61,76] | [53,66] | [48,60] | [44,55] | | [2.733,2.845] | [2.692,2.780] |
| [0.005,0.006] | [64,77] | [51,61] | [44,53] | [40,48] | [37,44] | | [2.669,2.768] | [2.628,2.704] |
| [0.006,0.007] | [55,64] | [43,51] | [38,44] | [34,40] | [32,37] | | [2.614,2.705] | [2.573,2.640] |
| [0.007,0.008] | [48,55] | [38,43] | [33,38] | [30,34] | [28,32] | | [2.566,2.650] | [2.525,2.586] |
| [0.008,0.009] | [43,48] | [34,38] | [29,33] | [27,30] | [25,28] | | [2.523,2.601] | [2.482,2.537] |
| [0.009,0.010] | [38,43] | [30,34] | [26,29] | [24,27] | [22,25] | | [2.484,2.558] | [2.442,2.494] |

The fuzzy first-stage sample size is taken as $\widetilde{n_1} = [4,6]$ and $\widetilde{n_1} = [9,11]$.It may be noted that the values of $\widetilde{n_2}$ are independent of the fuzziness in $\widetilde{n_1}$,where as the fuzziness in $\widetilde{n_1}$ is reflected only in the corresponding values of the variable factor $\tilde{k}$

**3.3.1. Illustration**

Consider the inspection of sterile drug vials produced in a pharmaceutical company. Tests such as sterility testing and chemical stability testing are costly and destroy the tested vials. Assume that about 1% of vials produced are defective. Since the tested vials cannot be used again and the exact defective level may change due to production variation, the proposed fuzzy mixed sampling plan is used for inspection. The plan is designed with a probability of acceptance of 95% and chain index $i = 3$.

**Solution:**

The process fraction defective at AQL is taken as the fuzzy interval
$\widetilde{p_1} = [0.009,0.010]$. The desired overall probability of acceptance at AQL is $p_{a1} = 0.95 \quad , i = 3$

As in the mixed sampling plan design, allocate the first stage acceptance probability as
$p'_{a1} = 0.65$ then the acceptance probability allocated for second stage sampling will be

$p''_{a1} = \frac{p_{a1} - p'_{a1}}{1 - p'_{a1}} = \frac{0.95 - 0.65}{1 - 0.65} = 0.857$

i.e. $p''_{a1} \cong 0.86$ (from Equation (13- 14))

From the table 4, $\tilde{k} = [2.484,2.558]$

For implementation $n_1 = FL(n_1) = 4$ , $n_2 = FL(n_2) = 26$, $k = FL(k) = 2.484$

Hence the fuzzy mixed sampling plan parameters are

$(\widetilde{n_1}, \widetilde{n_2}, \tilde{k}, i) = ([4,6], [26,29], [2.484,2.558], 3)$ with operational values

$(n_1, n_2, k, i) = (4,26,2.484,3)$

The first stage acceptance limit is $A = U - k\sigma = U - 2.484\sigma$

Operating rule:

(i)Draw $n_1$=4 units and compute sample mean $\bar{X}$.If sample mean $\bar{X} \leq U - 2.484\sigma$ ,accept the lot

(ii)Otherwise draw a sample $n_2 = 26$ units for attribute inspection

Inspect the second-stage sample and record the count of defective pieces $D$.The decision rules are as follows

(a)If $D = 0$,the lot shall be considered acceptable

(b)If $D > 1$,the lot shall be rejected

(c)If $D = 1$, the current lot is approved only when the preceding $i = 3$ lots were accepted; otherwise, it is rejected.

**3.4. Design of a mixed sampling plan indexed through LQL using fuzzy chain sampling as the attribute plan**

The following procedure is used to design a mixed sampling plan that incorporates a fuzzy chain sampling plan as attribute inspection stage, in order to satisfy fuzzy limiting quality level denoted by $\widetilde{p_2}$ and the corresponding probability of acceptance $p_{a2}$.The composite sampling plan is assumed to operate independently.

**1)Specification of fuzzy LQL and acceptance probability**

Let the limiting quality level be represented as an interval-valued fuzzy parameter $\widetilde{p_2} = [FL\ P_2, \mathrm{UL}P_2]$ and let $p_{a2}$ denotes the acceptance probability at LQL. Fix the chain index $i$

**2)Allocation of acceptance probability to first stage**

Divide the overall probability of acceptance, and assign a portion of it to the initial stage. Let it be $p'_{a2}$

**3) Selection of fuzzy first stage sample size and acceptance limit**

Select the first stage sample size as $\widetilde{n_1}$: $[FL(n_1), UL(n_1)]$

The fuzzy acceptance limit for the variable inspection stage is defined as (Equation 16 - Equation 17)

$$A = U - \left[Z(\widetilde{p_2}) + \frac{Z(p'_{a2})}{\sqrt{\widetilde{n_1}}}\right]\sigma \tag{16}$$

Equivalently the fuzzy variable factor is $\widetilde{k} = Z(\widetilde{p_2}) + \frac{Z(p'_{a2})}{\sqrt{\widetilde{n_1}}}$ (17)

For operational implementation the crisp values are taken as the lower bounds of fuzzy interval

$$n_1 = FL(n_1)\ \ ,\ \ n_2 = FL(n_2)\ ,\quad k = FL(k)$$

**4)Allocation of acceptance probability to the second stage**

Calculate the probability of acceptance $p''_{a2}$ allocated to the second stage attribute plan, using the relation (Equation 18)

$$p''_{a2} = \frac{p_{a2} - p'_{a2}}{1 - p'_{a2}} \tag{18}$$

**5) Determination of fuzzy second stage attribute sample size**

Identify the suitable sample size $\widetilde{n_2}$ for the second stage defined as $\widetilde{n_2}$ =$[FL(n_2), UL(n_2)]$ for a given chain index $i$ using the relation (Equation 19)

$$e^{-n_2 p} + n_2 p\ e^{-n_2 p(i+1)} = p''_{a2} \tag{19}$$

where $p \epsilon\ \widetilde{p_2} = [FL\ P_2, ULP_2]$ and $n_2 \epsilon\ \widetilde{n_2}$ =$[FL(n_2), UL(n_2)]$

**Table 5:** Values of fuzzy second stage sample size $(\widetilde{n_2})$ and variable factor $\tilde{k}$ for different chain indices (LQL based design).

| $\widetilde{p_2}$ | Values of $\widetilde{n_2}$ =$[FL(n_2), UL(n_2)]$ | | | | | | Variable factor $\tilde{k}$ | |
|---|---|---|---|---|---|---|---|---|
| | $i = 1$ | $i = 2$ | $i = 3$ | $i = 4$ | $i = 5$ | | $\widetilde{n_1} = [4,6]$ | $\widetilde{n_1} = [9,11]$ |
| [0.01,0.02] | [211,423] | [208,417] | [208,417] | [208,417] | [208,417] | | [1.1478,1.5866] | [1.4498,1.7800] |
| [0.02,0.03] | [141,211] | [139,208] | [139,208] | [139,208] | [139,208] | | [0.9748,1.3140] | [1.2768,1.5074] |
| [0.03,0.04] | [106,141] | [104,139] | [104,139] | [104,139] | [104,139] | | [0.8447,1.1411] | [1.1467,1.3345] |
| [0.04,0.05] | [85,106] | [83,104] | [83,104] | [83,104] | [83,104] | | [0.7389,1.0110] | [1.0409,1.2044] |
| [0.05,0.06] | [72,85] | [70,83] | [70,83] | [70,83] | [70,83] | | [0.6488,0.9051] | [0.9508,1.0985] |
| [0.06,0.07] | [63,72] | [61,70] | [61,70] | [61,70] | [61,70] | | [0.5698,0.8151] | [0.8718,1.0085] |
| [0.07,0.08] | [55,63] | [53,61] | [53,61] | [53,61] | [53,61] | | [0.4991,0.7361] | [0.8011,0.9295] |
| [0.08,0.09] | [49,55] | [47,53] | [47,53] | [47,53] | [47,53] | | [0.4348,0.6654] | [0.7368,0.8588] |
| [0.09,0.1] | [44,49] | [42,47] | [42,47] | [42,47] | [42,47] | | [0.3756,0.6010] | [0.6776,0.7944] |

### 3.4.1 Illustration

Consider the inspection of sterile drug vials produced in a pharmaceutical manufacturing company. Since sterile testing and chemical stability testing are costly and destructive in nature, the tested vials cannot be reused. To reduce inspection costs while maintaining the required quality standards, a mixed sampling plan is employed in which the initial stage employs variable testing while the subsequent stage applies a fuzzy chain attribute sampling plan.

The plan is designed based on the Limiting Quality Level $\widetilde{p_2}$ = [*0.03,0.04*] with overall probability of acceptance $p_{a2} = 0.05$ and the chain index $i = 1$

**Solution**

Here the first stage acceptance probability is taken as $p'_{a2} = 0.035$ ,leading to a conditional second stage probability $p''_{a2}$ = 0.0155 (from equation (18)).

From table 5, corresponding to $\widetilde{p_2}$ = [*0.03.0.04*] and $i = 1$ the fuzzy sampling scheme parameters are first stage sample size $\widetilde{n_1} = [4,6]$ , $\widetilde{n_2}$ =[106,141] and the fuzzy variable factor $\tilde{k}$ = [0.8447,1.1411].Taking the lower bound values for implementation, $n_1 = FL(n_1) = 4$ , $n_2 = FL(n_2) = 106$, $k = FL(k) = 0.8447$. Hence the fuzzy mixed sampling plan parameters are

$(\widetilde{n_1}, \widetilde{n_2}, \tilde{k}, i) = ([4,6], [106,141], [0.8447,1.1411], 1)$ with operational values

$(n_1, n_2, k, i) = (4,106,0.8447,1)$

The first stage acceptance limit is $A = U - k\sigma = U - 0.8447\sigma$

**Operating Rule**

(i)Draw $n_1$=4 units and compute sample mean $\bar{X}$.If sample mean $\bar{X} \leq U - 0.8447\sigma$ ,accept the lot

(ii)Otherwise draw a sample $n_2 = 106$ units for attribute inspection

Inspect the second-stage sample and record the count of defective pieces $D$.The decision rules are as follows

(a)If $D = 0$,the lot shall be considered acceptable

(b)If $D > 1$,the lot shall be rejected

(c)If $D = 1$, the present lot is accepted only when the preceding $i = 1$ lots were accepted; otherwise, it is rejected.

Thus, the proposed mixed sampling scheme provides strong consumer protection at the specified LQL while reducing the number of units subjected to destructive testing.

## 3.5 Minimax Risk Optimization Formulation of the Design Problem

Having developed the two design procedures in Sections III.3 and III.4, this section shows that each is a solution — or, in one case, a deliberately relaxed solution of a common minimax risk-constrained optimization problem, making explicit the optimization structure both procedures implicitly draw on.

### 3.5.1 General Worst-Case Risk Formulation

Let $\theta = (n_1, n_2, k, i)$ denote the parameters of the fuzzy mixed sampling plan, and let

$p_a(p; \theta) = p_a'(p) + [1 - p_a'(p)] \cdot p_a''(p)$

denote the overall probability of acceptance of the composite plan at true fraction defective p, where $p_a'$ is the first-stage (variables) acceptance probability governed by the acceptance limit $A = U - k\sigma$, and $p_a''$ is the second-stage (fuzzy chain sampling) acceptance probability governed by Equation (15) or (19), as applicable. This is the same composite OC structure underlying both Section III.3 (with the AQL subscript "1") and Section III.4 (with the LQL subscript "2").

Lemma 1 (Monotonicity of the composite OC function). For fixed θ, $p_a(p; \theta)$ is monotonically non-increasing in p.

*Proof.* Each term of the second-stage acceptance probability, $e^{-n_2 p}$ and $n_2 p\, e^{-n_2 p(i+1)}$, in Equations (15) and (19), is non-increasing in p for $p > 0$, $n_2 > 0$, $i \geq 1$, since a larger p strictly reduces the probability of encountering zero or one defective in a chain-sampling scheme. Likewise, the first-stage probability $p_a'(p)$, obtained from the acceptance limit $A = U - k\sigma$ via the normal-distribution transform in Equations (13) and (16)–(17), is non-increasing in p, since a larger true fraction defective strictly reduces the probability that the sample mean falls at or below A. As $p_a(p; \theta)$ is a convex combination of two non-increasing functions of p, it is itself non-increasing in p. ■

By Lemma 1, for any fuzzy interval $\tilde{p} = [pL, pU]$ representing ambiguity in the true fraction defective, the worst-case acceptance behaviour over $\tilde{p}$ is attained at one of the two interval endpoints: the upper endpoint pU if protection against producer's risk is required (since $1 - p_a(p; \theta)$ increases with p), or the lower endpoint pL if protection against consumer's risk is required (since $p_a(p; \theta)$ is largest at the smallest p).

### 3.5.2 General Minimax Risk-Constrained Program

The fuzzy mixed sampling plan design problem is stated in general as

$$\text{Min } [n_2, k] \text{ FASN}(\theta) \text{ s.t. } \text{Rmax}(\theta) \leq \gamma,\ n_1, i, p_a' \text{ fixed},\ n_2 \in \mathbb{Z}+,\ k > 0 \quad \text{(III.5.1)}$$

where Rmax(θ) denotes the relevant worst-case risk (producer's or consumer's) evaluated at the corresponding interval endpoint identified above, and γ denotes the associated risk tolerance (α for producer's risk, a $1 - p_{a2}$-type target for consumer's risk, as defined in each section). Here $n_1$ (first-stage sample size),$i$(chain index), and $p_a'$ (first-stage probability allocation) are treated as pre-specified design inputs — consistent with how they are selected in Steps 1–2 of III.3 and Steps 1–3 of III.4.

The objective FASN is chosen, rather than $n_2$ alone, because the units under inspection (sterile drug vials) are subjected to destructive testing: every unit sampled, at either stage, is destroyed and cannot be returned to the lot. The relevant cost measure is therefore the expected number of units destroyed per lot, which for this mixed plan is

$$\text{FASN}(\theta) = n_1 + (1 - p_a') \cdot n_2$$

Since the $n_1$ first-stage units are destroyed on every lot, while the $n_2$ second-stage units are destroyed only on the fraction $(1 - p_a')$ of lots that fail to clear the first stage and proceed to chain sampling. As n1 and $p_a'$ are fixed design inputs, FASN is an affine, strictly increasing function of $n_2$ alone; consequently, minimizing FASN(θ) and minimizing $n_2$ yield the identical optimal design, so the program solves for the remaining parameters ($n_2$, k) that jointly satisfy the single active risk constraint at minimum expected destructive sample size.

### 3.5.3 Section III.3 as the Producer's-Risk Instance

Section III.3 is precisely program (III.5.1) applied with the producer's worst-case risk constraint. There, $\tilde{p}_1 = [p_1L, p_1U]$ is the fuzzy AQL, the acceptance-probability allocation $p_a1'$ and first-stage sample size $\tilde{n}_1$ are fixed by design (Steps 1–2 of III.3), the acceptance limit and fuzzy variable factor $\tilde{k}$ are obtained from equation (13) by evaluating $Z(\tilde{p}_1)$ at its endpoints, and the fuzzy second-stage sample size $\tilde{n}_2 = [FL(n_2), UL(n_2)]$ is obtained by solving equation (15) with p evaluated at the two endpoints of $\tilde{p}_1$ (Table 4). By Lemma 1, the worst-case producer's risk over $\tilde{p}_1$ is attained at $p = p_1U$.

For the illustrative design ($\tilde{p}_1 = [0.009, 0.010]$, i = 3), the exact solution of equation (15) at $p_1U = 0.010$ gives n2 = 26, the smaller of the two tabulated values; the exact solution at $p_1L = 0.009$ gives $n_2 = 29$. The operational choice $n_1 = 4$, $n_2 = FL(n_2) = 26$, $k = FL(k) = 2.484$, taken in Illustration III.3.1, is therefore the exact minimax-safe solution of program (III.5.1): it satisfies the target $p_a1$ at the worst-case endpoint $p_1U$, and exceeds it at $p_1L$, so producer protection holds across the entire fuzzy AQL band. No relaxation is involved in this design.

### 3.5.4 Section III.4 as the Consumer's-Risk Instance, With A Cost-Driven Relaxation

Section III.4 addresses program (III.5.1) applied with the consumer's worst-case risk constraint. There, $\tilde{p}_2 = [FL\ p_2, UL\ p_2]$ is the fuzzy LQL, the acceptance-probability allocation $p_{a2}'$ and first-stage sample size $\tilde{n}_1$ are fixed by design (Steps 1–3 of III.4), the fuzzy variable factor $\tilde{k}$ is obtained from equations (16) – (17) by evaluating $Z(\tilde{p}_2)$ at its endpoints, and the fuzzy second-stage sample size $\tilde{n}_2$ is obtained by solving equation (19) with $p \in \tilde{p}_2$ (Table 5). By Lemma 1, the worst-case consumer's risk over $\tilde{p}_2$ is attained at the lower endpoint, $p_2L$.

For the illustrative design ($\tilde{p}_2$ = [0.03, 0.04], $i = 1$), the exact solution of equation (19) at the worst-case point $p_2L$ = 0.03 gives $n_2$ = 141, k = 1.1411 — the minimax-safe values that guarantee $pa_2 \leq 0.05$ across the entire fuzzy LQL band. The exact solution at $p_2U$ = 0.04 gives the smaller values $n_2$ = 106, k = 0.8447.

Because the units under test are costly, destructively tested sterile drug vials, Illustration III.4.1 adopts the smaller values, $n_1$ = 4, $n_2$ = FL($n_2$) = 106, k = FL(k) = 0.8447, rather than the minimax-safe values above. This is a deliberate, cost-driven departure from the strict minimax solution of program (III.5.1), made to limit the number of vials destroyed per lot. Its effect can be quantified directly: evaluating the composite OC function at the true worst-case point $p_2L$ = 0.03 with $n_2$ = 106 gives an achieved overall acceptance probability of approximately $p_{a2} \approx$ 0.081, against the nominal design target of $p_{a2}$ = 0.05 — a relative increase in consumer risk of roughly 60% at the low end of the fuzzy LQL band, relative to what the minimax-safe design ($n_2$ = 141) would deliver.

### 3.5.5 Summary

Section III.3 implements the exact minimax-optimal solution of program (III.5.1) at the fuzzy AQL, with no gap between the theoretical worst-case guarantee and the operational design. Section III.4 implements a cost-constrained relaxation of the same program at the fuzzy LQL, trading a known and quantified reduction in worst-case consumer protection for a smaller destructive sample size, which is appropriate given the cost of sterile vial testing. Presenting both cases within the same minimax framework makes this distinction explicit: the AQL-based design can be read as a strict risk guarantee, while the LQL-based design should be read as a cost-risk trade-off with a stated, bounded departure from that guarantee.

## 4. Results and Discussion

The results presented in Tables 4 and 5 demonstrate the behaviour of the proposed fuzzy mixed sampling plan under AQL- and LQL-based design conditions. The fuzzy interval-valued operating parameters provide additional information regarding the uncertainty associated with the sampling decisions while maintaining the desired producer's and consumer's risks.

The results presented in Table 4 are graphically illustrated in figure 3, which shows the variation of the fuzzy acceptance constant with respect to the fuzzy AQL interval.

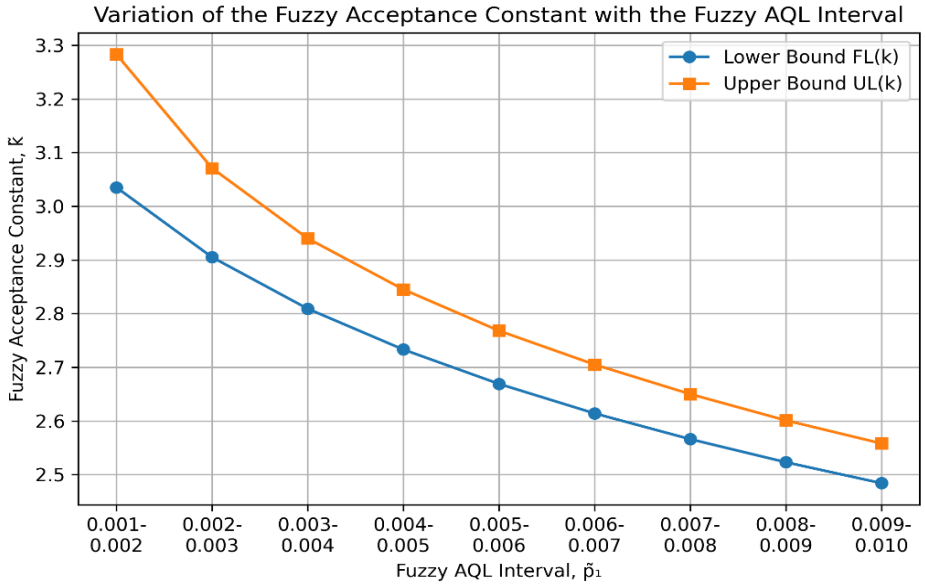


**Figure 3:** Variation in lower and upper bounds of the fuzzy acceptance constant with fuzzy AQL intervals

Figure 3 illustrates a decreasing trend in both the lower and upper bounds of the fuzzy acceptance constant as the fuzzy AQL interval increases. The upper bound consistently remains higher than the lower bound, reflecting uncertainty in the acceptance criteria under varying quality levels.

- As the fuzzy AQL interval $\widetilde{p_1}$ increases, the fuzzy variable factor $\tilde{k}$ decreases gradually. Since the first-stage acceptance limit is given by $A = U - k\sigma$, a smaller value of $k$ produces a less restrictive acceptance limit. Consequently, conforming lots have a higher probability of being accepted during the variable inspection stage, thereby reducing unnecessary second-stage inspection.

- The fuzzy second-stage sample interval $\widetilde{n_2}$ =$[FL(n_2), UL(n_2)]$ decreases as the AQL interval increases. This indicates that fewer units require attribute inspection, thereby reducing destructive testing and improving inspection efficiency without altering the specified acceptance probability.

- when the first stage sample size increases from $\tilde{n_1} = [4,6]\ to\ \tilde{n_1} = [9,11]$, the bandwidth of $\tilde{k}$ becomes narrower. The reduction in interval width indicates lower uncertainty in the estimated acceptance constant and therefore improves the precision and consistency of the sampling decision.

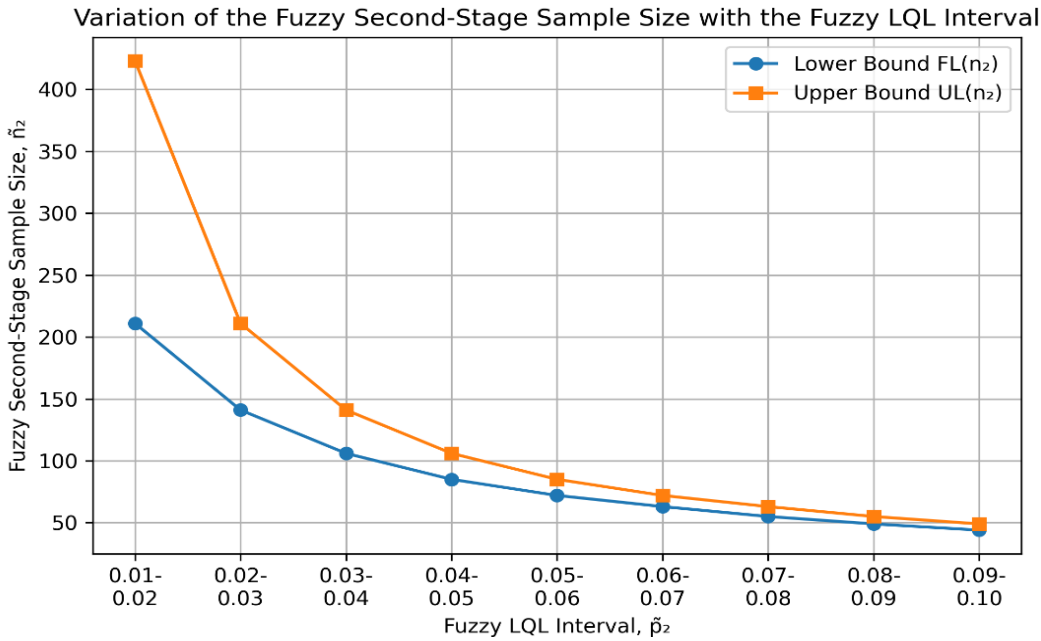


**Figure 4:** Variation in lower and upper bounds of fuzzy second-stage sample size with fuzzy LQL intervals.

Figure 4 illustrates a decreasing trend in both the lower and upper bounds of the fuzzy second-stage sample size as the fuzzy LQL interval increases. The difference between the bounds gradually narrows, indicating reduced sampling uncertainty and smaller sample size requirements at higher fuzzy LQL levels.

The results presented in Table 5 are graphically illustrated in figure 4. The variation of the fuzzy second-stage sample size with respect to the fuzzy LQL interval is discussed below.

- As the fuzzy LQL increases both $FL(n_2), and\ UL(n_2)$ decrease significantly. This shows that less inspection is required when the lot quality is poor.
- Increasing the fuzzy first stage sample size from $\tilde{n_1} = [4,6]\ to\ \tilde{n_1} = [9,11]$,improves the precision of acceptance and consequently the second stage attribute inspection size reduces slightly enhancing the overall inspection efficiency.
- Only minor variations are observed for different chain indices $(i = 1,2,3,4,5)$ , indicating that the proposed fuzzy mixed sampling plan is stable with respect to the chain sampling parameter. Hence, the operating characteristics remain consistent for different values of the chain index.
- Compared with the AQL-based design, the LQL-based design provides a stricter inspection strategy for poor-quality lots. This improves consumer protection by increasing the probability of rejecting nonconforming lots while maintaining the flexibility introduced through interval-valued fuzzy parameters.

## 4.1. Limitations and practical challenges

Despite these advantages, the proposed framework has several limitations. The operational parameters are fixed at the lower bounds of the fuzzy intervals for conservative implementation, so the plan does not exploit the full range of information contained in the fuzzy sets (except for the LQL-based design, where this lower-bound choice is a cost-driven relaxation rather than the conservative/minimax-safe value — see Section III.5.4). The design tables are restricted to the chain indices and fuzzy interval combinations considered in this study, and the analysis assumes independence between the outcomes of successive lots in the chain sampling stage, which may not hold under strong process correlation. The pharmaceutical case study is illustrative and is based on an assumed defect proportion rather than validated production data, so the choice of sampling parameters would need to be confirmed against actual process capability data before regulatory adoption. From a practical standpoint, implementing the plan in a pharmaceutical setting would also require quality personnel to interpret interval-valued acceptance

decisions, which may need additional training and revised standard operating procedures compared with conventional single-valued sampling plans.

Overall, the proposed fuzzy mixed sampling plan effectively combines variable and chain attribute inspection under interval-valued uncertainty. The fuzzy operating parameters obtained in Tables 4 and 5 demonstrate that the proposed approach reduces destructive inspection effort while maintaining reliable lot acceptance decisions. Furthermore, the interval representation enables decision makers to account for uncertainty in the quality level without modifying the fundamental mixed sampling framework.

## 5. Conclusion

This study proposed a fuzzy mixed sampling plan indexed through both the AQL and LQL, using a fuzzy chain sampling plan as the second-stage attribute inspection procedure, for sterile drug vial testing where destructive testing is unavoidable. The AQL-based design facilitates acceptance of good-quality lots through fuzzy acceptance limits and first-stage sample sizes; the LQL-based design strengthens rejection of poor-quality lots through the second-stage attribute inspection. For the illustrative case, the AQL-based design yielded ($n_1$, $n_2$, k, i) = (4, 26, 2.484, 3) at $p_1$ = [0.009, 0.010] with $p_{a1}$ = 0.95, and the LQL-based design yielded (4, 106, 0.8447, 1) at $p_2$ = [0.03, 0.04] with $p_{a2}$ = 0.05. Section III.5 shows the AQL-based design to be the exact minimax-optimal solution of the underlying risk-constrained optimization problem, while the LQL-based design deliberately adopts a smaller, cost-driven sample size that trades a quantified amount of worst-case consumer protection for reduced destructive testing.

As the fuzzy defect level increases, the required second-stage sample size falls sharply from $n_2$ = [191, 383] at $p_1$ = [0.001, 0.002] to $n_2$ = [38, 43] at $p_1$ = [0.009, 0.010] for $i = 1$, while k decreases from [3.035, 3.283] to [2.484, 2.558], giving less restrictive limits for conforming lots. A larger first-stage sample, from [4, 6] to [9, 11], narrows k's interval width and improves precision, with only minor variation across chain indices $i = 1$ to 5.

Overall, the methodology offers an efficient, practical quality-control framework for sterile drug vial testing without compromising reliability. The design tables are restricted to the chain indices and fuzzy intervals considered here, and the case study relies on an assumed defect proportion rather than validated production data. Operational parameters are fixed at the lower bounds of the fuzzy intervals -conservative for the AQL design, but a cost-driven relaxation of the minimax-safe value for the LQL design (Section III.5.4). Future work could extend the plan to multistage, double, or group sampling schemes, benchmark it against existing fuzzy chain sampling plans, incorporate neutrosophic logic to model indeterminacy, and validate the framework on real industrial data.

**Conflict of Interest:** The Authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

**Ethical Approval:**

This study does not involve any human participants or animals, and therefore ethical approval is not required.

**Informed Consent:**

Informed consent is not applicable as this study does not involve human participants.

**Data Availability Statement:**

Data Sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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