

SELECTION OF A BAYESIAN DOUBLE SAMPLING PLAN THROUGH MARKOV DEPENDENCE METHOD IN DRUG DISCOVERY

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Abstract

Most of the pharmaceutical firms have worked hard to maintain quality in their manufacturing products like medicines and biological instruments using the principles of statistical quality control to optimize the fault model. In this field, one of the pioneering statistical methods is acceptance sampling by attributes. A sampling plan is used to assess the quality of goods, keep an eye on the quality of the materials, and confirm whether or not the yields are defect-free or not. When posterior knowledge about the parameter is known, the Bayesian strategy provides a more robust statistical method for reaching a suitable conclusion. In this article a new Bayesian double sampling plan under stochastic modeling was established. This is achieved by various characteristics of sampling plan explicit by its random variable and its probability function. This plan is studied through the Gamma- Poisson model to safeguard both the producer and consumer by minimizing the Average Sample Number and Total Cost. Necessary tables and figures are constructed for the selection of optimal plan parameters and suitable illustrations are provided that are applicable under pharmaceutical industries.

Keywords: Acceptance Sampling, Bayesian double sampling plan, Gamma-Poisson, Pharmaceutical Industry, Stochastic Process, Transition Probability Matrix.

1. INTRODUCTION

The pharmaceutical industry directly deals with human's health by its medical needs and drug development towards human safety. All countries formulate policies to safeguard public health and implement regulations for monitoring the production of pharmaceutical products. Developing countries put significant effort to deliver quality goods to their citizens. The book "Quality management in the medicines industry: philosophy and essential elements"[21] describes the fundamental principles of quality assurance (QA) and the core elements of Good Manufacturing Practices (GMP), which are integral to both production and quality control management. These include of persons, premises, materials, documentation, validation, self-inspection, hygiene, and equipment. "Good practices in production and quality control" offers instructions on specific steps that quality control and production staff should independently undertake to implement core principles of Quality Assurance. Commonly, World Health Organization (WHO) suggests three types of sampling plans: n , p and r . The primary objective of the n -plan is the determination

of the sample size, whereas the p -plan emphasizes the maximum number of defects and the r -plan focuses on the rejection number.

Many industries commonly use acceptance sampling plan to meet the inspection quality requirements for ever increasing global demand. The nature of inspection may be destructive or non-destructive depends on its characteristics of its products to fulfil the inspections is often impractical that resulting the lot is accepted/rejected, therefore move on to acceptance sampling plan is more efficient. Acceptance sampling is divided into two primary categories: (1) attribute sampling plan and (2) variable sampling plan. Lot-by-lot acceptance sampling for attributes was studied by many authors under a variety of sampling designing methods, such as single, double, sequential, continuous, chain, skip-lot and other related sampling plans each having its own advantage and its limitations. Hald [7] and Schilling [17] developed the sampling plan parameters based on the unity value approach. Several authors have contributed to the foundational principles of quality control, including Calvin T.M [1], Cameron [2], Dodge H.F. and Roming H.G. [3], Edwin B wilson *et. al.*[4], Golub [5], Peach P.[16], Gunether [20]. The theory behind traditional sampling plans by attributes is based on the basic assumption that the nonconforming process fraction or lot is a constant, implying that the manufacturing process is steady. Conventional sampling strategies cannot be used in these situations since the judgement about the submitted lots must take into account and it's not consider between lots variations and within lots variations. Bayesian sampling plans are a sophisticated technique to statistical sampling that uses Bayesian probability theory to make conclusions and judgments about observed data. Choosing a prior distribution for the lot fraction nonconforming has been discussed by Vijayaraghavan *et al.* [19], selecting a prior distribution for a metric quality characteristic of the production process has been studied by Loganathan *et al.* [11]. When sampling from a Poisson distribution, the gamma distribution is a conjugate prior, according to Bayesian theory. The gamma distribution is the conjugate prior to the average number of nonconformities per unit. When sample units are randomly selected from a process, the number of nonconformities in the sample is distributed based on the Poisson equation. Under these circumstances, the operating characteristic (OC) function of SSP by characteristics labelled as gamma-Poisson SSP has been mathematically expressed by Hald [7]. Implication of production and monitoring techniques in Bayesian Single sampling plan using Gamma- Zero Inflated Poisson distribution studied by Kaviyarasu and Sivakumar [9]. Bayesian single sampling plan using gamma prior were provided by Suresh K.K and Latha [18]. The fundamental concepts of quality control have been explored by several researchers, including Guptha S.K. *et. al.*[6], Kaviyarau *et. al.*[8] [10], Lord *et. al.*[12], Moskowitz *et. al.*[15]. A novel control strategy was presented by Fallahnezhad and Nasab [13] addressing the acceptance sampling problem. Fallahnezhad [14] provided a minimal angle method-based Markov chain acceptance sampling plan. In this work gives tables to determine the c_1, c_2, c_3, c_4, n (minimum sample size) and minimum cost of the Bayesian Acceptance Sampling Plan under the circumstances of using the Gamma-Poisson distribution.

2. TRANSITION PROBABILITY MATRIX FOR ACCEPTANCE SAMPLING

A stochastic process can have several branches. A markov chain is a type of stochastic process that is used to determine the best threshold value to accept or reject a lot. This concept actually gave rise to the idea of modelling the acceptance sampling using a markovin method. Let $P = p_{ij}$ represent the transition probability matrix for the finite state space S with discrete-time. A transition probability matrix depicts the single-step process of moving from one state to another. It includes all of the information required to understand how the process moves across the states.

2.1. Assumptions

- The entries of matrixes are all non-negative.
- In the matrix each row equals to one.

$$p_{11} + p_{12} + p_{13} + \dots + p_{1n} = 1 \tag{1}$$

The three states of the problem are designed as follows:

- Accept the lot when the batch is in good state.
- Reject the lot when the batch is in bad state.
- Continue the inspection when it is in between the upper and lower thresholds.

Every phase is viewed as a state of the transition matrix P , which comprises the probabilities of accepting the batch p_{12} , rejecting the batch p_{13} , and continues the process p_{11} . The matrix P is an absorbing Markov chain where the states are known to be transient (continue inspection) and absorbing (reject or accept the lot). Finding the optimal threshold values for the sampling plan is the aim of this Markovian technique. Wilson and Burgess [19], Specified the block form for the transition probability matrix is arranged as follows

$$P = \begin{bmatrix} A & O \\ R & Q \end{bmatrix} \tag{2}$$

Here

A = An identity matrix representing the probability of remains in a state.

O = The matrix representing the probabilities of escaping an absorbing state (always zero).

R = The matrix containing all probabilities of going from a non-absorbing state to an absorbing state. (i.e., finished or scrapped product).

Q = The square matrix contacting the transition probability of going from a non-absorbing state to another non-absorbing state.

2.2. Total Cost

The expected total cost associated with the inspection policy can be expressed using the equation 3, which is employed to calculate the total cost. The acceptance cost multiplied by the probability of accepting the batch at stage 1. The rejection cost is calculated by multiplying the rejection cost by the probability of rejecting the batch at stage 2.

The average total cost for double sampling plan is given as

$$E(TC) = \text{Acceptancecost} + \text{Rejectioncost} + \text{Inspectioncost} \tag{3}$$

where,

Acceptance cost = cost of defective item \times lot size \times probability of accepting the lot

Rejection cost = cost of batch rejection \times probability of rejecting lot

Inspection cost = ((Number of times the lot inspected with n_1 items \times Number of samples in stage 1) + (Number of times the lot inspected with n_2 items \times Number of samples in stage 2 \times probability that the second sample is taken during the first sample inspected)) \times the cost of the defective items.

3. CONSTRUCTION OF A BAYESIAN DOUBLE SAMPLING PLAN USING THE MARKOV CHAIN METHOD

Using a Markov chain in a Bayesian double sampling enables the modelling of sequential decision-making, allowing for the integration of prior knowledge and the updating of beliefs as new data becomes available. This dynamic approach enhances decision-making under uncertainty, reducing risks in the sampling process. Additionally, Markov chains help to accurately compute the posterior probabilities of accepting or rejecting a lot by considering previous sample outcomes, leading to more efficient.

3.1. Markov Chain Procedure for Bayesian Double Sampling Plan

- Initially, inspect n_1 items from the lot, this items collected through random sampling
- Set the threshold values (lower threshold r_1 , upper threshold r_2) for the n_1 samples
- If the defective items (d_1) items from the sample are below or equal to the lower threshold (r_1) value, the lot will be accepted
- If the defective items (d_1) items from the sample are above the upper threshold (r_2) value, the lot will be rejected
- If defective items (d_1) in between the two threshold values, then take a second sample of size n_2
- Set the threshold values (lower threshold r_3 , upper threshold r_4) for the n_2 samples
- If defective items (d_2) of the sample are below the lower threshold (r_3) value, the lot will be accepted
- If defective items (d_2) of the sample are above the upper threshold (r_4) value, the lot will be rejected
- If defective items (d_2) in between threshold values, return to first sample size of n_1 items are to be inspected, such a continuous process is called as a double sampling decision-making process under markov decision

Each stages of the plan is defined as a states.

Step 1: For the lot, the first stage acceptance policy ought to be implemented.

Step 2: For the lot, the Second stage acceptance policy ought to be implemented.

Step 3: The lot should be accepted.

Step 4: The lot should be rejected.

3.2. Transition Probability Matrix

The lot's transition probability matrix is given as follows,

$$\begin{bmatrix} 0 & P_{12} & P_{13} & P_{14} \\ P_{21} & 0 & P_{23} & P_{24} \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

Rearranging the matrix gives the fundamental matrix.

$$N_{ij} = \begin{bmatrix} \frac{1}{1-P_{12}P_{21}} & \frac{P_{21}}{1-P_{12}P_{21}} \\ \frac{P_{12}}{1-P_{12}P_{21}} & \frac{1}{1-P_{12}P_{21}} \end{bmatrix} = m_{ij}$$

The probability of long-term absorption ζ is

$$\zeta = \begin{bmatrix} \frac{1+P_{12}P_{23}}{1-P_{12}P_{21}} & \frac{P_{21}P_{13}+P_{23}}{1-P_{12}P_{21}} \\ \frac{P_{14}+P_{12}P_{24}}{1-P_{12}P_{21}} & \frac{P_{21}P_{14}+P_{24}}{1-P_{12}P_{21}} \end{bmatrix}$$

The elements of ζ matrix, ζ_{13} is probability of accepting the batch at stage 1 and ζ_{14} is probability of rejecting the batch at stage 1.

3.3. Transition Probability Matrix for Gamma – Poisson

The Poisson distribution with parameter $np = \lambda$, where λ is the average number of nonconformities per unit, is used to distribute the random variable, when it is taken at random from a production process that generates from a continuous stream of lots.

The Poisson distribution is a suitable model for the number of nonconforming units in the sample, as noted by Hald [7] for $p < 0.10$ and by Schilling [17] when n is large and P is small such that $np < 5$.

$$P_{(n,p)}(d) = \frac{e^{-np}(np)^d}{d!} \quad \text{for } d = 0, 1, 2, \dots$$

A random variable, say L , must be introduced to represent the randomly varying distribution parameter when the distribution parameter λ is not constant but rather varies at random from lot to lot.

This random variable is distributed according to a gamma distribution, which is the Poisson distribution's conjugate distribution.

The prior distribution of L 's density function can be found as follows:

$$f_{(a,m)}(\lambda) = \frac{e^{-a\lambda} a^m \lambda^{m-1}}{\Gamma(m)} \quad \text{for } 0 \leq \lambda < \infty, a, m > 0$$

Where $a = \frac{m}{\bar{\lambda}}$, with $E[L] = \bar{\lambda}$ and m is the shape

When production is not stable, L is independently distributed, and according to Hald [7] the Gamma-Poisson probability distribution can be determine by the following

$$p = \sum_{d=0}^n \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m$$

Where

n = number of observations

p = proportion defectives

m = shape parameter for gamma prior

d = number of defectives

To determine the probability of reaching each state, the cumulative Gamma-Poisson distribution is used as

$$p(r_1 < d < r_2) = p_{11} = \sum_{d=0}^{n_1} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m - p_{12} \quad (4)$$

$$p(d > r_2) = p_{13} = \sum_{d=0}^{r_2} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m = 1 - p_{12} \quad (5)$$

$$p(d \leq r_1) = p_{12} = \sum_{d=0}^{r_1} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m \quad ; x = 0, 1, \dots, r_1 \quad (6)$$

$$p(r_3 < d < r_4) = p_{21} = \sum_{d=0}^{n_2} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m - p_{23} \quad (7)$$

$$p(d > r_4) = p_{24} = \sum_{d=0}^{r_4} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m = 1 - p_{23} \quad (8)$$

$$p(d \leq r_3) = p_{23} = \sum_{d=0}^{r_3} \frac{(m+d+1)!}{d!(m-1)!} \left(\frac{np}{np+m}\right)^d \left(\frac{m}{np+m}\right)^m \quad ; x = 0, 1, \dots, r_3 \quad (9)$$

Where

p_{12} = The probability that the second sample from the lot will be taken while the first sample is being inspected.

p_{13} = Probability that a lot will be accepted after the initial sample inspection.

p_{14} = Probability that a lot will be rejected after the initial sample inspection.

p_{21} = Probability that the first sample is taken during second sample inspection.

p_{23} = Probability that a lot will be accepted after the second sample inspection.

p_{24} = Probability that a lot will be rejected after the second sample inspection.

The following expression represents the average total cost associated with the lot acceptance policy of the double sampling plan:

$$E(\text{Total cost}) = (cs \times N \times p \times \zeta_{13}) + (rc \times \zeta_{14}) + (m_{11} \times n_1 + m_{22} \times n_2 \times p_{12})I$$

Where

$$\zeta_{13} = \frac{p_{13} + p_{12}p_{23}}{1 - p_{12}p_{21}}$$

$$\zeta_{14} = 1 - \zeta_{13}$$

cs = Cost of defective item

N = Lot Size

p = Incoming quality

m_{11} = Number of times the lot inspected with n_1 items

m_{22} = Number of times the lot inspected with n_2 items

4. DIFFERENT PRIOR VALUES FOR DIFFERENT THRESHOLD VALUES

This analysis is carried out to showcase the implementation of the proposed methodology in the formulation of an acceptance sample design. Consider the following problem: $AQL = 0.05$, $LQL = 0.1$. The alternate values of m among the present ones provide various combinations.

In the case $N = 1500$, $cs = 1$, $p = 0.05$, $I = 2$, $rc = 100$, $n_1 = 75$, $n_2 = 65$.

Table 1: The feasible values of $r_1, r_2, r_3, r_4, E(n)$ and average cost values for $m = 1$

When $p_1 = 0.02$ Probability of accepting the lot	When $p_2 = 0.10$ Probability of rejecting the lot	r_1	r_2	r_3	r_4	$E(n)$	Average Cost
0.66	0.85	0	2	0	2	92	266.56
0.74	0.84	0	3	0	2	99	279.16
0.84	0.73	1	3	1	3	89	257.23
0.90	0.70	1	4	1	4	97	271.65
0.91	0.62	2	4	2	4	87	251.31
0.91	0.62	2	4	2	5	88	253.09
0.95	0.54	3	5	3	5	85	256.89
0.95	0.54	3	5	3	6	86	248.22

Table 2: The feasible values of $r_1, r_2, r_3, r_4, E(n)$ and average cost values for $m = 3$

When $p_1 = 0.02$ Probability of accepting the lot	When $p_2 = 0.10$ Probability of rejecting the lot	r_1	r_2	r_3	r_4	$E(n)$	Average Cost
0.61	0.97	0	2	0	2	85	253.67
0.71	0.97	0	3	0	2	91	264.85
0.87	0.91	1	3	1	3	88	253.77
0.94	0.90	1	4	1	4	98	272.58
0.95	0.82	2	4	2	4	90	255.58
0.95	0.81	2	4	2	5	91	258.81
0.98	0.71	3	5	3	5	90	255.82
0.98	0.70	3	5	3	6	91	257.57

Table 3: The feasible values of $r_1, r_2, r_3, r_4, E(n)$ and average cost values for $m = 5$

When $p_1 = 0.02$ Probability of accepting the lot	When $p_2 = 0.10$ Probability of rejecting the lot	r_1	r_2	r_3	r_4	$E(n)$	Average Cost
0.60	0.99	0	2	0	2	81	247.84
0.72	0.99	0	3	0	2	87	256.62
0.88	0.95	1	3	1	3	86	249.16
0.95	0.95	1	4	1	4	96	267.82
0.95	0.88	2	4	2	4	89	254.48
0.96	0.88	2	4	2	5	91	258.11
0.90	0.77	3	5	3	5	92	258.28
0.99	0.77	3	5	3	6	94	262.30

The odds of accepting and rejecting the lot probability values are shown in Table 1 as $m = 1$. The least sample size obtained in this table is 85, with the minimum total cost is 248.22. However, the probability of acceptance and rejection the lot fails to satisfy the said conditions to align with the requirements. Further, Table 2 displays $m = 3$ for both the lot's acceptance and rejection probabilities are studied and obtained the smallest sample size in this table 2 is 85, and the minimum total cost is 253.67.

However, the probability of accepting and rejecting the lot fails again to satisfy the basic conditions to align with the requirements. In Table 3, threshold values shows a significant improvement in the said conditions 1, 4, 1 and 4 and meets its basic conditions, so the feasible sample is 96 and the total cost is 267.82. Thus the sample size is fixed as 96 with its corresponding probability values.

5. NUMERICAL ILLUSTRATION

In a pharmaceutical company with continuous production, a Quality Engineer (QE) plan to check the solubility of capsules, in the lot, there are 1500 capsules, and the capsules dissolve within three seconds.

QE fixed the $AQL = 0.05$, $LQL = 0.1$, the cost of a defective item (cs) = 1, the proportion of the defective items in a batch is (p) = 0.05, the cost of inspecting an item in the batch (I) = 2, the cost of batch rejection (rc) = 100, and the first and second samples are $n_1 = 75$, $n_2 = 65$.

Table 4: Capsules dissolving time for first sample

Time	0	1	1	0	2	3	1	0	1	1	0	0	2	1	0	0	1	1	2	0	1	3	2	0
P/F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Time	1	2	1	0	0	1	1	0	5	1	3	0	2	1	2	0	1	3	1	2	2	1	2	2
P/F	P	P	P	P	P	P	P	P	F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Time	0	1	0	0	1	1	1	3	0	1	0	2	3	1	0	4	1	1	1	2	0	2	2	1
P/F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	F	P	P	P	P	P	P	P	P	P

Table 5: Capsules dissolving time for second sample

Time	2	3	1	0	1	1	1	0	1	1	0	0	0	1	1	1	0	0	1	3	0	1
P/F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Time	0	1	1	1	4	0	1	0	0	1	3	1	2	2	1	0	1	3	1	2	2	1
P/F	P	P	P	P	F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Time	0	0	1	1	1	3	1	3	0	1	0	2	3	0	1	0	2	3	1	2	0	
P/F	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	

Where

P/F = Pass or Fail

R software is utilized to generate the Gamma-Poisson data (mean = 0.405 < Standard deviation = 0.667) and to draw samples through random sampling. The samples are presented in Table 4 and Table 5. In this table, dissolving seconds ranging from 0 to 3 seconds are deemed acceptable, whereas times exceeding 3 seconds are considered to have failed the inspection.

Proceed to the second sample if the previous one has two defects. The lot gets accepted because the second sample only contains one defect. For the first sample, the lower threshold value is 1, and the upper threshold value is 4. The lower threshold value is 1 for the second sample, and the upper threshold value is 4 for the second sample, where $m = 5$.

6. CONCLUSION

In this article, a new sampling plan methodology is developed under Markovian matrix method as an improved method of inspection under attribute quality characteristics of Gamma-Poisson distribution. Bayesian double sampling plan incorporates more benefits through sample size and its acceptance number which are determined with prior knowledge towards improving decision-making under uncertainty. Transition probability matrix allows for a probabilistic view of decision routes by calculating the likelihood of changing from one state to another state. By using this matrix, the inspection cost is optimized, leading to a better comprehension of potential results. Suitable tables are developed with numerical examples are given to demonstrate Pharmaceutical industry application for the drug discovery of this study.

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