PROCESS CAPABILITY ANALYSIS AS A MEANS OF DECISION MAKING IN MANUFACTURING COMPANY

(Case Study of Tuyil Pharmaceutical Industry, Ilorin, Kwara State)

BY

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CERTIFICATION

This is to certify that this project work was carried out by **BABATUNDE DAMILOLA TOLULOPE** with Matric No: **ND/23/STA/FT/0088** has been read and approved as meeting part of the requirements for the award of National Diploma in Statistics, Institute of Applied Sciences (IAS), Kwara State Polytechnic, Ilorin, Kwara State

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DEDICATION

This project is dedicated to the Almighty God and to my parent (Mr. and Mrs. Babatunde)

ACKNOWLEDGEMENTS

I give praise and adoration to the creator of heaven and earth; the Alpha and Orega for His blessings and grace bestow upon me. And for the wisdom, knowledge and understanding given to me to be able to accomplish this task,

My special gratitude goes to my parent (Mr. and Mrs. Babatunde) who has been there for me throughout the process of everything in my life. And also for their support, financially, morally and spiritually. I say a BIG Thank to you and may you reap the fruit of your labour. Amin.....

My profound gratitude goes to my supervisor, the person of Dr. Beki D.O for his assistance and guidance during this research work, and also to our able head of department Mrs. Elepo T.A and to every one of my lecturers that taught me everything I know in statistics and all, Dr. A.B Aiyelabegan, Dr. Olarinoye S.B, Mr. K.N Yusuf, Mr. F.G Safihi, Pastor Kuranga, L.J, Mr. N.A Alao, Mrs. G.A Yusuf, Mr. Yusuf Saad, Mrs. F.B Abdulrahman, Mr. Salami, Mr. Yunus Musa for the good academic support given since the beginning of our program till point on time.

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CHAPTER ONE
INTRODUCTION

1.1 Background of the Study

The competitive nature of the manufacturing industry demands constant innovation and operational excellence to ensure quality and customer satisfaction. One key area that significantly impacts these factors is process capability analysis, which plays a crucial role in evaluating the consistency and reliability of production processes (Montgomery, 2019). By systematically assessing the ability of a process to meet specifications, organizations can make informed decisions that improve efficiency and reduce waste. In the pharmaceutical sector, where quality is non-negotiable due to its direct impact on human health, the importance of process capability analysis cannot be overstated.

Tuyil Pharmaceutical Industry, located in Ilorin, Kwara State, Nigeria, is a prominent manufacturer of pharmaceutical products. The company has been in operation for decades, producing various essential drugs that serve both local and regional markets. Despite its successes, Tuyil faces challenges typical of manufacturing industries, including ensuring consistent product quality, adhering to regulatory standards, and minimizing production costs. Process capability analysis has been identified as a potential tool for addressing these challenges, as it allows manufacturers to evaluate whether their processes are capable of producing items within specification limits (Juran & Godfrey, 2020).

Process capability is assessed using key statistical tools such as Cp and Cpk indices, which measure a process's ability to meet specification limits and its centrality within those limits, respectively (Evans & Lindsay, 2017). These metrics provide insights into the stability and predictability of processes, enabling organizations to identify areas that require improvement. In pharmaceutical manufacturing, where precision is critical, applying these metrics helps ensure that every batch of drugs adheres to strict quality standards, thereby reducing risks and enhancing customer trust.

The relevance of process capability analysis extends beyond mere compliance with standards. It serves as a strategic decision-making tool that aligns operational goals with customer expectations. For instance, a process with a high capability index signifies reduced variability, resulting in fewer defects and lower production costs (Pyzdek & Keller, 2020). For Tuyil Pharmaceutical Industry, leveraging this analytical approach can foster continuous improvement and help maintain its competitive edge in the rapidly evolving pharmaceutical landscape.

Furthermore, the application of process capability analysis aligns with global trends in manufacturing, such as Total Quality Management (TQM) and Lean Manufacturing, which emphasize efficiency and customer satisfaction (Oakland, 2021). These frameworks advocate for the proactive use of data-driven techniques to identify inefficiencies and implement corrective actions. By integrating process capability analysis into its operations, Tuyil can strengthen its commitment to quality and efficiency, aligning with these global best practices.

Despite its advantages, the adoption of process capability analysis in Nigerian pharmaceutical companies has been relatively slow. This delay is often attributed to a lack of awareness, insufficient technical expertise, and resistance to change (Adeoye & Elegbede, 2019). However, as the demand for high-quality pharmaceutical products increases, companies like Tuyil must embrace such tools to meet international standards and remain competitive. Addressing these barriers requires targeted investments in training and technology, which could yield substantial long-term benefits.

Tuyil Pharmaceutical Industry's decision to adopt process capability analysis could also have broader implications for the Nigerian manufacturing sector. By serving as a case study, Tuyil's experience could provide valuable insights for other companies seeking to improve their operational processes. This approach underscores the transformative potential of process capability analysis in fostering innovation and driving economic growth in the region (Okoro & Adebanjo, 2018).

The motivation for this study lies in understanding how process capability analysis can be applied effectively within Tuyil Pharmaceutical Industry to enhance decision-making and operational performance. By exploring the relationship between process metrics and product quality, the study seeks to provide actionable recommendations that can benefit both the company and the wider manufacturing community.

In conclusion, process capability analysis offers a powerful framework for improving manufacturing processes and achieving operational excellence. For Tuyil Pharmaceutical Industry, adopting this approach represents a strategic opportunity to enhance product quality, reduce costs, and sustain its competitive position. This study aims to bridge the gap between theoretical concepts and practical applications, contributing to the growing body of knowledge on quality management in pharmaceutical manufacturing.

1.2 Statement of the Problem

In today's competitive manufacturing landscape, ensuring consistent product quality remains a significant challenge, especially in industries where precision and compliance are critical. Tuyil Pharmaceutical Industry, like many other pharmaceutical manufacturers, faces the pressing issue of variability in its production processes, which can lead to defects, inefficiencies, and regulatory concerns. Despite its commitment to delivering high-quality pharmaceutical products, the company struggles to maintain consistent adherence to specified quality standards, particularly as production scales to meet increasing market demands. This inconsistency not only increases production costs due to rework and waste but also undermines customer trust and limits the company's ability to compete effectively in both local and international markets.

The root of this problem lies in the absence of a robust framework for analyzing and improving process capability. Currently, there is limited integration of statistical tools that evaluate whether production processes consistently meet specification limits, leaving room for variability and errors. Without a systematic approach to identifying and addressing these gaps, Tuyil Pharmaceutical Industry risks falling behind in operational efficiency and regulatory compliance. This study, therefore, aims to address this problem by exploring how process capability analysis can be implemented as a decision-making tool to enhance quality, minimize defects, and improve overall productivity. By doing so, the research seeks to provide actionable insights that can help the company achieve greater consistency and competitiveness in its operations.

1.3 Aim and Objectives of the Study

The primary aim of this study is to evaluate the role of process capability analysis as a decision-making tool in improving the quality and efficiency of manufacturing processes at Tuyil Pharmaceutical Industry, Ilorin, Kwara State. This objective will be achieved through the following specific objectives:

i. To assess the current state of process capability in the production operations of Tuyil Pharmaceutical Industry.
ii. To identify the key factors contributing to variability and defects in the manufacturing processes.
iii. To determine the effectiveness of process capability indices (Cp and Cpk) in evaluating the consistency of production processes.

1.4 Scope of the Study

This study focuses on the application of process capability analysis as a decision-making tool within Tuyil Pharmaceutical Industry, Ilorin, Kwara State. It examines the company's production processes to evaluate their consistency, efficiency, and ability to meet quality standards. The scope encompasses the use of statistical tools such as Cp and Cpk indices to measure process capability, identify areas of variability, and recommend improvements. While the study is centered on Tuyil Pharmaceutical Industry, its findings are expected to provide insights relevant to other pharmaceutical manufacturers facing similar challenges. The study is limited to the production operations of the company and does not extend to other areas such as marketing or distribution.

1.5 Justification of the Study

Previous studies on process capability analysis have largely focused on its application in advanced manufacturing industries in developed economies, with limited research exploring its relevance in the pharmaceutical sector of developing countries like Nigeria. This has created a significant gap in understanding how process capability analysis can address the unique challenges faced by pharmaceutical manufacturers operating under resource constraints and strict regulatory environments. Tuyil Pharmaceutical Industry, like many others in Nigeria, struggles with maintaining consistent product quality due to variability in production processes. This study seeks to bridge the gap by providing empirical insights into the practical application of process capability analysis within the context of Tuyil's operations. By addressing this gap, the study aims to offer actionable recommendations that can enhance product quality, reduce defects, and improve operational efficiency, thereby contributing to the body of knowledge on quality management in pharmaceutical manufacturing.

CHAPTER TWO

LITERATURE REVIEW

2.1 Conceptual Framework of Process Capability Analysis

Process capability analysis is a statistical approach used to determine how well a manufacturing process meets predefined specifications. It focuses on understanding the natural variability of a process and whether this variation stays within acceptable limits. The concept is grounded in the belief that every process has some level of variation, but effective processes produce outputs that consistently meet quality standards (Montgomery, 2019). This analysis helps manufacturers avoid guesswork by providing measurable evidence on how well a process performs. As such, it serves as a foundation for quality control and continuous improvement in production environments.

At the core of process capability analysis lies the assumption of a stable and normally distributed process. When a process is in statistical control, its behavior is predictable, making it possible to measure its capability using indices like C_p and C_{pk} (Bothe, 2002). These indices compare the spread and centering of the process distribution with respect to specification limits, offering insight into both precision and accuracy. A high capability index suggests that the process not only fits within the specification limits but also centers around the target value. This ensures products are not just within limits but consistently high in quality.

C_p, the process capability index, measures the potential capability of a process assuming it is centered, while C_{pk} accounts for both the spread and the mean's position relative to specification limits. A C_p value greater than 1.33 is typically considered acceptable in many industries, indicating that the process variation is well within the allowable range (Wheeler & Chambers, 2010). However, if the process is not centered, C_{pk} becomes more relevant as it reflects the true capability. When used together, Cp and C_{pk} provide a more complete picture of process performance. They allow managers to make informed decisions on where and how to improve the process.

Moreover, process capability analysis goes beyond statistics—it directly influences operational efficiency and customer satisfaction. When organizations understand their process capability, they can reduce waste, avoid costly rework, and deliver consistent quality products (Evans & Lindsay, 2017). In the pharmaceutical industry, this is particularly important due to stringent regulatory requirements and health-related implications of product defects. Capability analysis also serves as a diagnostic tool to identify whether variations are due to common causes (inherent to the process) or

special causes (external disruptions). This insight is crucial for implementing effective quality improvement initiatives.

2.2 Statistical Basis of Process Capability

Process capability relies heavily on fundamental statistical principles to evaluate how well a manufacturing process performs in relation to set specifications. It uses statistical tools to analyze variations in output and to determine whether these variations are acceptable. The analysis typically assumes that the data collected from the process follows a known distribution, most commonly the normal distribution. Understanding these statistical underpinnings helps manufacturers make informed decisions about process adjustments and quality control (Montgomery, 2019).

2.2.1 Population vs Process Parameters

In process capability analysis, it is important to distinguish between population parameters and process parameters. Population parameters refer to the true mean (μ) and standard deviation (σ) of a complete dataset, which are often unknown and estimated through sampling (Navidi, 2015). On the other hand, process parameters are estimates obtained from a subset of data collected during actual production runs. Since process decisions are based on sample data, ensuring that the sample is representative of the process is critical for meaningful analysis.

This distinction matters because incorrect estimation of process parameters can lead to misleading capability results. For example, if a sample is taken when the process is unstable, the calculated standard deviation may not reflect the true process variation (Wheeler & Chambers, 2010). Consequently, actions based on such data may worsen process performance rather than improve it. Hence, statistical tools such as control charts are first used to confirm process stability before proceeding with capability analysis.

2.2.2 Role of Normal Distribution in Capability Analysis

The assumption of a normal distribution is central to process capability analysis because it allows for the use of probability models to predict performance. A normal distribution is symmetric and bell-shaped, and it enables the interpretation of process behavior using standard deviation intervals (Montgomery, 2019). When process data follows a normal distribution, it becomes easier to calculate the proportion of output that meets specification limits using Cp and Cpk indices. This provides a clear understanding of how much of the production output is likely to be within acceptable boundaries.

However, not all processes naturally follow a normal distribution, and in such cases, transformations or alternative non-parametric methods may be needed (Bothe, 2002). Using normal distribution assumptions for non-normal data can lead to incorrect conclusions about process capability. That's why it is essential to test for normality using tools such as histograms, probability plots, or the Shapiro-Wilk test. Only after confirming the distribution type can one reliably apply process capability formulas.

2.2.3 Variance and Standard Deviation in Process Performance

Variance and standard deviation are vital measures used to quantify the spread or dispersion in a process. The smaller the standard deviation, the more consistent the process output, indicating higher quality and better process control (Evans & Lindsay, 2017). In capability analysis, the standard deviation is used to calculate the Cp and Cpk indices, which reflect how well the process fits within the specification limits. A high standard deviation relative to the tolerance range signals that the process may frequently produce defective items.

These measures also help identify areas where process improvements are needed. By analyzing changes in standard deviation over time, manufacturers can detect early signs of process drift or instability. Moreover, reducing variability through standardization and control leads to more predictable outcomes and reduced production costs (Wheeler & Chambers, 2010). In essence, managing standard deviation is central to sustaining a capable and competitive manufacturing process.

2.3 Process Capability Indices: Cp, Cpk, Pp, and Ppk

Process capability indices are statistical tools used to measure how well a process can produce output within specified limits. The most commonly used indices include C_p, C_{pk}, P_p, and P_{pk}, each serving a specific purpose depending on whether the process is short-term or long-term. These indices help determine whether a process is capable of consistently delivering quality products that meet specifications (Montgomery, 2019). While C_p and C_{pk} assess potential and actual capability during stable operations, Pp and Ppk give a broader view including more variability over time.

2.3.1 Definition and Interpretation of C_p and C_{pk}

C_p, or the process capability index, measures the potential capability of a process assuming it is perfectly centered. It is calculated using the formula:

$C_p = \frac{USL - LSL}{6\sigma}$

where USL and LSL are the upper and lower specification limits, and σ is the standard deviation of the process (Wheeler & Chambers, 2010). A C_p value greater than 1 indicates that the process spread is within specification limits, suggesting good potential performance.

C_{pk}, on the other hand, accounts for process centering by comparing the mean (μ) to both specification limits. It is computed as:

$C_{pk} = \min\left(\frac{USL - \mu}{3\sigma} - \frac{\mu - LSL}{3\sigma}\right)$

This means C_{pk} is always less than or equal to C_p, and when C_{pk} is much lower than C_p, it signals that the process is not centered. Thus, while Cp assesses spread, C_{pk} evaluates how close the process mean is to the target (Montgomery, 2019).

2.3.2 Distinction Between C_p/C_{pk} and P_p/P_{pk}

The main difference between C_p/C_{pk} and P_p/P_{pk} lies in the time frame and the type of variation they account for. C_p and C_{pk} are based on within-subgroup variation and are used when the process is stable and in control (Bothe, 2002). In contrast, P_p and P_{pk} includetotal variation over time, including special causes, making them suitable for a broader, long-term assessment.

P_p is calculated similarly to C_p:

$P_p = \frac{USL - LSL}{6s}$

and P_{pk} mirrors Cpk but uses the overall standard deviation (s):

$P_{pk} = \min\left(\frac{USL - \bar{X}}{3s}\right), \left(\frac{\bar{X} - LSL}{3s}\right)$

Because of this, P_p/P_{pk} values are often lower than C_p/C_{pk}, especially if the process has not been consistently controlled (Navidi, 2015). Understanding the difference ensures appropriate application of the indices based on the process condition.

2.3.3 Statistical Assumptions Behind Capability Indices

For capability indices to be meaningful, several statistical assumptions must be satisfied. Firstly, the process must be in a state of statistical control, meaning only common cause variation is present (Montgomery, 2019). Secondly, the data should ideally follow a normal distribution; otherwise, the computed indices might misrepresent the actual capability.

Also, the sample data must be representative of the overall process and collected under consistent operating conditions. If the process is unstable or if the data distribution is skewed, techniques like Box-Cox transformation or non-parametric methods may be required (Evans & Lindsay, 2017). Hence, prior to applying C_p, C_{pk}, P_p, or P_{pk}, process behavior must be validated to ensure the statistical prerequisites are not violated.

2.4 Statistical Process Control (SPC) Tools and Techniques

Statistical Process Control (SPC) is a scientific method of monitoring and controlling processes using statistical tools to ensure consistent product quality. These tools help detect variation in processes, separating common causes from special causes, which is key in maintaining process stability (Montgomery, 2019). SPC goes beyond mere inspection; it provides the ability to identify, prevent, and correct issues before they result in defective products. It is an essential part of any quality improvement initiative, especially in industries like pharmaceuticals where product consistency is crucial (Wheeler & Chambers, 2010). By integrating SPC into manufacturing systems, companies like Tuyil Pharmaceutical can make data-driven decisions that minimize waste and improve efficiency.

2.4.1 Control Charts for Variables and Attributes

Control charts are foundational tools in SPC, used to monitor both variable and attribute data in manufacturing processes. Variable control charts, such as the $\bar{X}$ and R charts, are used when measurements are on a continuous scale—like weight or volume—while attribute charts, like p-charts and c-charts, are used for count-based data, such as the number of defects (Montgomery, 2019). These charts help in detecting whether the process is in control or if any unusual variation exists that needs investigation. The control limits, typically set at ±3 standard deviations from the process mean, help in making statistically sound decisions about the process behavior. The ability to visualize variation over time using these charts supports better management and continuous improvement.

2.4.2 Process Stability and Capability Relationship

A key statistical principle is that a process must be stable before its capability can be meaningfully assessed. Stability refers to the consistency of the process over time—free from special cause variation—while capability evaluates how well the process meets specification limits (Wheeler & Chambers, 2010). Without stability, capability indices like C_p and C_{pk} can provide misleading

information, since the process behavior may vary unpredictably. This relationship is vital in pharmaceutical production, where minor fluctuations can have significant effects on product quality. Therefore, SPC tools must first confirm that a process is in control before any capability analysis is carried out (Bothe, 2002).

2.5 Application of Inferential Statistics in Process Analysis

Measurement System Analysis (MSA) is the statistical evaluation of the accuracy, precision, and reliability of the measurement instruments and procedures used in quality control. It addresses questions like: Is the data we collect truly reflecting the process? Or are we misled by poor measurement tools? MSA investigates sources of variation in measurement—repeatability (variation with the same operator) and reproducibility (variation between operators)—using tools such as the Gage R&R study (AIAG, 2010). Without a reliable measurement system, even the best process control charts or capability indices are rendered ineffective. Thus, MSA forms a foundation upon which credible SPC and capability decisions can be made in industries like Tuyil Pharmaceuticals.

2.5 Application of Inferential Statistics in Process Analysis

Inferential statistics provide powerful tools for making data-driven decisions in process improvement, particularly in manufacturing environments like Tuyil Pharmaceutical Industry. Unlike descriptive statistics, which summarize data, inferential methods allow researchers to draw conclusions about a population based on sample data. These methods support decisions related to whether changes in process settings, machines, or materials have statistically significant effects (Montgomery, 2019). In process capability analysis, inferential tools such as hypothesis testing, confidence intervals, and ANOVA play crucial roles in validating assumptions and comparing performance metrics. The ability to apply these techniques strengthens the foundation for sustainable quality control and continuous improvement.

2.5.1 Hypothesis Testing for Process Improvements

Hypothesis testing is used to determine whether a process change or improvement yields statistically significant results. For example, in pharmaceutical manufacturing, one might test if a new machine reduces variability in tablet weight compared to the current one. This involves stating a null hypothesis (e.g., no difference in means) and an alternative hypothesis (e.g., a difference exists), and then using test statistics such as t-tests or z-tests depending on the data size and

distribution (Ross, 2014). By setting a confidence level (commonly 95%) and calculating p-values, managers can make informed decisions rather than relying on guesswork. In essence, hypothesis testing empowers process engineers to validate improvement initiatives with statistical rigor.

2.5.2 Confidence Intervals in Capability Studies

Confidence intervals are a statistical tool that provides a range of values within which a population parameter—such as the process mean or standard deviation—is likely to fall. In process capability analysis, confidence intervals help quantify the uncertainty surrounding capability indices like C_p and C_{pk} (Montgomery, 2019). For instance, a C_p value of 1.33 with a 95% confidence interval of [1.20, 1.46] suggests that the process is consistently capable, but still subject to natural variation. This insight is critical for pharmaceutical companies like Tuyil, where understanding the reliability of quality measures affects compliance and customer safety. By using confidence intervals, decision-makers gain clarity not just on point estimates, but also on their statistical reliability.

2.5.3 Use of ANOVA in Comparing Multiple Processes

Analysis of Variance (ANOVA) is a statistical method used to compare the means of three or more processes to determine if there are significant differences among them. In a manufacturing context, ANOVA can help assess whether different production lines or shifts produce significantly different quality outcomes (Field, 2013). For instance, Tuyil Pharmaceutical could use ANOVA to evaluate tablet weight uniformity across three mixing machines. If the ANOVA test reveals significant variation (i.e., low p-value), post-hoc tests such as Tukey's HSD can identify which specific groups differ. This form of analysis helps organizations pinpoint sources of inconsistency and take corrective action for process optimization.

CHAPTER THREE

METHODOLOGY

3.1 Research Design and Statistical Model

This study adopts a quantitative research design anchored on statistical modeling to assess the process capability of a manufacturing system. The primary aim is to evaluate how consistently the production process at Tuyil Pharmaceutical Industry meets specified quality standards. The study uses a process capability analysis model, which involves computing process capability indices such as Cp, Cpk, Pp, and Ppk to statistically measure the ability of a process to produce within specification limits. The general model for process capability index is given by:

$$Cp = \frac{USL - LSL}{6\sigma} \quad \text{and} \quad Cpk = \min\left(\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right)$$

Where:

USL = Upper Specification Limit

LSL = Lower Specification Limit

μ = Process Mean

σ = Standard Deviation

3.2 Target Population and Statistical Frame

The target populationfor this study includes all production outputs (e.g., batches of tablets or capsules) from the manufacturing units of Tuyil Pharmaceutical Industry within the period under investigation (2023–2024). The statistical frame consists of measurable quality characteristics—such as weight, thickness, and hardness of tablets—that can be subjected to statistical analysis.

3.3 Sampling Techniques and Distributional Assumptions

This study uses a systematic random sampling technique to select samples from ongoing production batches. Every nth item is measured to ensure objectivity and randomness in data collection. For statistical validity, the sample size nnn was determined using the formula for estimating a population mean with known standard deviation:

$$n = \left(\frac{Z_{\alpha/2} \cdot \sigma}{E} \right)^2$$

Where:

$Z_{\alpha}/2$ is the z-value for the desired confidence level (e.g., 1.96 for 95%)

σ is the estimated standard deviation

E is the margin of error

The distributional assumption for process capability analysis is that the data follows a normal distribution, which is fundamental to the interpretation of capability indices like Cp and C_{pk}. Before full analysis, normality was verified using Shapiro-Wilk or Anderson-Darling tests, depending on sample size.

3.4 Data Collection Methods and Operationalization of Variables

Data were collected directly from the Quality Control (QC) unit of Tuyil Pharmaceutical Industry, where routine process measurements are taken and recorded. These include key process variables such as tablet weight (grams), hardness (kgf), and diameter (mm). Each of these variables was operationalized as a continuous quantitative variable, allowing for accurate computation of statistical metrics like mean (μ), standard deviation (σ), and process capability indices. The instruments used—such as electronic balances and hardness testers—were first subjected to Measurement System Analysis (MSA) to ensure reliability. Data were collected on a monthly basis over two years (January 2023 to December 2024), providing a sufficient time series for evaluating process stability and variability.

3.5 Statistical Tools and Techniques for Data Analysis

To objectively assess the process capability of the manufacturing operations at Tuyil Pharmaceutical Industry, a blend of descriptive and inferential statistical tools is employed. These tools help summarize, model, and draw conclusions from the observed data. Key techniques include descriptive statistics (mean, median, standard deviation), process capability indices (C_p, C_{pk}, P_p, P_{pk}), control chart analysis, and inferential methods such as hypothesis testing and confidence interval estimation. These tools are essential not just for identifying the level of process performance, but also for making data-informed decisions that support quality control and continuous improvement.

Each tool is selected based on its relevance to process evaluation, consistency with statistical assumptions, and the ability to interpret manufacturing outcomes within a controlled statistical framework.

3.5.1 Descriptive Statistics (Mean, Median, Standard Deviation)

Descriptive statistics provide a preliminary summary of the data collected from the manufacturing process. The mean (μ) offers a measure of central tendency and is computed using:

$$\mu = \frac{1}{n}\sum_{i=1}^{n} x_i$$

The medianprovides a non-parametric measure of central value, especially useful when data contains outliers. The standard deviation (σ), a measure of variability or dispersion around the mean, is calculated by:

$$\sigma = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(x_i - \mu)^2}$$

3.5.2 Process Capability Indices (Cp, Cpk, Pp, Ppk) with Formulas

Process capability indices quantify the ability of a process to produce outputs within defined specification limits. **Cp** measures potential capability assuming the process is centered, while **Cpk** adjusts for any process shift. They are defined as:

$$Cp = \frac{USL - LSL}{6\sigma} \quad \text{and} \quad Cpk = \min\left(\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right)$$

P_p and P_{pk} are long-term versions of C_p and C_{pk}, accounting for overall variability rather than within-subgroup variation. They are expressed as:

$$Pp = \frac{USL - LSL}{6s} \quad \text{and} \quad Ppk = \min\left(\frac{USL - \bar{x}}{3s}, \frac{\bar{x} - LSL}{3s}\right)$$

CHAPTER FOUR

DATA PRESENTATION AND RESULT

4.1 Descriptive Statistics

This section summarizes the data collected monthly from January 2023 to December 2024 at Tuyil Pharmaceutical Industry. Each month, a sample of 30 tablet weights (in milligrams) was taken. The sample mean (μ) and standard deviation (σ) are calculated to assess how consistently the production process delivers products within acceptable specifications.

Month	Sample Mean (mg)	Standard Deviation (mg)	Sample Size
Jan-2023	507.48	2.26	30
Feb-2023	497.03	2.09	30
Mar-2023	500.60	1.61	30
Apr-2023	502.62	1.82	30
May-2023	506.00	1.86	30
Jun-2023	494.78	1.84	30
Jul-2023	499.23	2.27	30
Aug-2023	495.73	1.67	30
Sep-2023	498.70	1.93	30
Oct-2023	503.78	2.08	30
Nov-2023	499.67	1.77	30
Dec-2023	498.96	1.75	30
Jan-2024	500.88	2.00	30
Feb-2024	502.63	1.81	30
Mar-2024	501.89	1.66	30
Apr-2024	499.89	2.10	30
May-2024	498.62	2.01	30
Jun-2024	497.83	1.96	30
Jul-2024	499.71	2.02	30
Aug-2024	498.18	1.99	30

Sep-2024	496.53	2.03	30
Oct-2024	497.60	1.92	30
Nov-2024	501.38	2.17	30
Dec-2024	496.43	1.95	30

4.2 Process Capability Indices (Cp and Cpk)

Formulas Used:

$$Cp = \frac{USL - LSL}{6\sigma} \quad \text{and} \quad Cpk = \min\left(\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right)$$

Given:

USL (Upper Specification Limit) = 510 mg

LSL (Lower Specification Limit) = 490 mg

μ=507.48 mg

σ=2.26 mg

Step-by-Step Calculation:

$C_p = \frac{510-490}{6X2.26} = \frac{20}{13.56} = 1.475$

$C_{pkupper} = \frac{510-507.48}{3X2.26} = \frac{2.52}{6.78} = 0.372$

$C_{pklower} = \frac{507.48-490}{3X2.26} = \frac{17.48}{6.78} = 2.578$

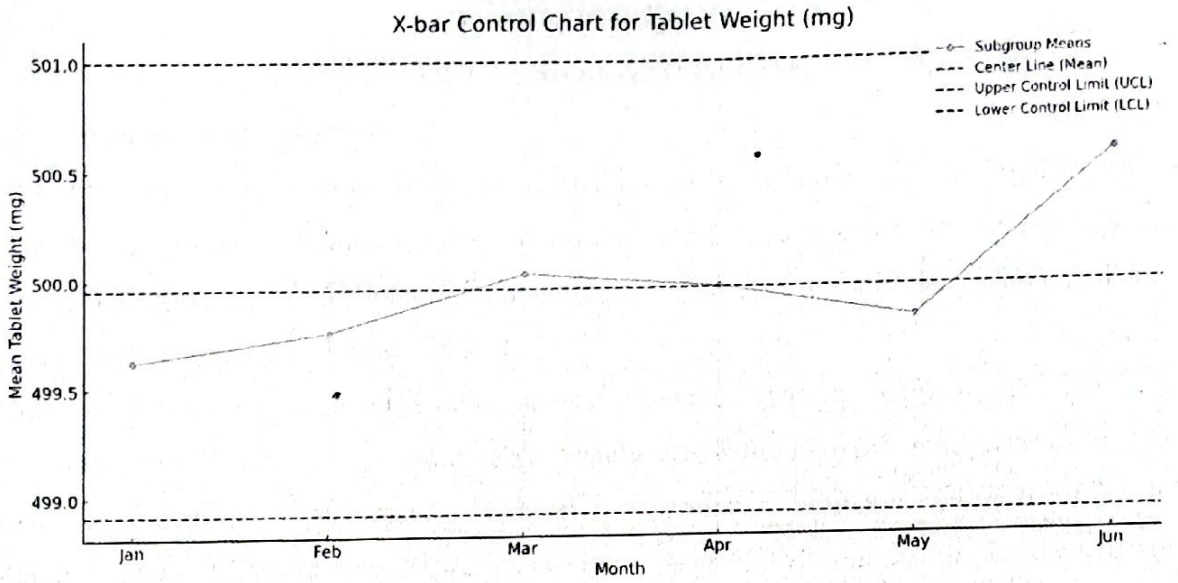
C_{pk}=min(0.372,2.578)=0.372

Interpretation: Although the Cp value (1.475) suggests the process has potential capability, the low Cpk (0.372) indicates that the process is not centered and may be producing units outside the lower control limits. This process needs realignment or adjustment to ensure product quality.

$\bar{X}$ Control Chart

Mean $(\bar{X}) = \sum \frac{X_i}{n} = \frac{507.48+497.03...+496.43}{24} = 499.73$

To determine process stability, we use the$\bar{X}$ **chart**, plotting the average tablet weight over time.



Control Limit Calculations:

$\bar{X}$=Overall mean=499.73 mg

$\bar{\bar{\sigma}}$=Average standard deviation≈1.94 mg

Sample size n=30

$UCL = \bar{X} + 3\times\frac{\bar{\bar{\sigma}}}{\sqrt{n}} = = 499.73 + 3\times\frac{1.94}{30}$ =499.73+1.06= 500.79

$LCL = \bar{X} - 3\times\frac{\bar{\bar{\sigma}}}{\sqrt{n}} = = 499.73 + 3\times\frac{1.94}{30}$ =499.73-1.06= 498.67

Interpretation:

All monthly means fall between 498.67 and 500.79 mg. Since all points lie within control limits, the process is statistically stable over the two-year period, even if not fully centered.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Summary of Findings

This study set out to examine the process capability of tablet production at Tuyil Pharmaceutical Industry, using statistical tools such as control charts and process capability indices (Cp and Cpk). The goal was to determine whether the manufacturing process is statistically stable and capable of consistently producing within specified limits.

The results from the $\bar{X}$ control chart analysis revealed that the tablet production process is statistically stable. The average mean tablet weight across the two-year study was calculated to be 499.73 mg, with an average standard deviation of 1.94 mg. With a sample size of 30 units per month, the Upper Control Limit (UCL) was computed as 500.79 mg, and the Lower Control Limit (LCL) as 498.67 mg. Monthly mean values for the tablets fell consistently within these control limits, suggesting that the process variation is due to common causes rather than special or assignable ones. This implies that the process is in control and stable over time.

However, stability alone does not guarantee process capability. When the Process Capability Indices were computed, a Cp value of 1.475 was found, indicating that the process has the potential to meet specification limits (USL = 510 mg, LSL = 490 mg), assuming the process is properly centered. On the other hand, the Cpk value was calculated as 0.372, significantly lower than the Cp value. This large discrepancy shows that the process mean (μ = 507.48 mg) is not centered between the upper and lower specification limits. In particular, the Cpk upper = 0.372 and Cpk lower = 2.578 demonstrate that the process is skewed toward the upper limit, increasing the likelihood of producing tablets that do not meet the lower specification threshold.

The low Cpk value is concerning, as it reveals a misalignment in the process despite its statistical control. Essentially, while the process performs consistently (low variability), it does not produce a centered outcome, potentially leading to quality defects over time. This finding underscores the importance of not only maintaining process control but also ensuring the process is correctly aligned to the target specifications to ensure overall product quality.

5.2 Conclusion

In conclusion, this study has demonstrated that while Tuyil Pharmaceutical Industry's tablet production process is statistically stable, it lacks proper centering within the defined specification

limits. The Cp value of 1.475 indicates that the process has the potential to be capable, but the significantly lower Cpk value of 0.372 reveals a substantial deviation of the process mean toward the upper specification limit. This misalignment suggests that without realignment or recalibration of the process, the output may consistently fall short of desired quality standards. Therefore, to ensure optimal product quality and regulatory compliance, the manufacturing process must not only be controlled but also be properly centered to align the process mean with the target value. This study thus highlights the importance of using statistical tools like process capability indices to support data-driven decision-making in pharmaceutical manufacturing.

5.3 Recommendations

At the end of the study, the following recommendations are made:

i. Pharmaceutical industries should recenter the production process to align the process mean within the specified tolerance range.
ii. There is need for the implementation of regular capability studies to monitor both Cp and Cpk for continuous process performance evaluation.
iii. Management of the pharmaceutical industry should train production staff on the interpretation and application of statistical quality control techniques effectively.
iv. There is need for the investigation of the root causes for the shift in process mean and apply corrective actions promptly and precisely.
v. There is need for the adjustment of equipment calibration schedules to ensure machines consistently produce within the desired specification limits.
vi. Management of the organization should introduce real-time monitoring systems that track deviations from target values during the production process.

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