

SIX SIGMA METHODOLOGY AND PROCESS CAPABILITY BY MINITAB SOFTWARE - OVERVIEW AND CASE STUDIES

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ABSTRACT

In an era driven by data-centric decision-making, achieving excellence in quality control and process optimization is paramount—especially within regulated industries like pharmaceuticals. Minitab, a powerful statistical software package, plays a vital role in implementing Six Sigma methodologies, particularly the DMAIC (Define, Measure, Analyze, Improve, Control) framework. This article explores how Minitab enhances quality assurance, facilitates data analysis, and supports regulatory compliance through its comprehensive suite of statistical tools including control charts, hypothesis testing, regression analysis, and Design of Experiments (DOE). Its real-time Statistical Process Control (SPC) features further enable proactive quality management by detecting deviations and triggering automated alerts, thus ensuring product safety and GMP adherence. The article also examines Minitab's role in root cause analysis, process capability studies, and pharmaceutical development, emphasizing its contribution to continuous improvement and operational excellence. One of the most well-known indices is process capability (C_p), also known as the precision index. C_p measures the ratio between the specification width (difference between the Upper Specification Limit (USL) and Lower Specification Limit (LSL)) and the process spread (represented by 6σ). Through real-world applications and integration with Six Sigma practices, Minitab proves to be an indispensable tool for professionals striving to minimize variability, reduce defects, and elevate product quality.

KEYWORDS: MINITAB, Process Capability, Six Sigma Methodology, Statistical Analysis, Control Charts

INTRODUCTION

Minitab is a robust and flexible statistical software program that is widely used in process improvement, quality assurance, and data analysis. Professionals and companies may analyse data, make data-driven choices, and improve the quality of goods and services with Minitab's user-friendly interface and extensive statistical toolkit. Minitab provides a broad array of features, such as importing data from multiple sources, conducting hypothesis tests, performing regression analysis, creating control charts, and analyzing process capability. Its strong alignment with Six Sigma methodologies, particularly the DMAIC (Define, Measure, Analyze, Improve, Control) framework, makes it a preferred tool for professionals seeking to improve processes and elevate quality standards across diverse industries.

Minitab is used by professionals in a variety of industries, such as manufacturing, healthcare, finance, and education, to extract insights from data and promote ongoing development. Minitab is appropriate for both novice and seasoned statisticians due to its accessibility through a variety of license choices, as well as its comprehensive learning materials and tutorials. Minitab is still a useful tool that helps people and companies use data to accomplish their objectives and keep a competitive advantage in their respective industries since data analysis is still crucial to decision-making.

Minitab is a statistical, data analysis, and process improvement software utilized by organizations globally to enhance quality and lower costs. It is a comprehensive data analysis tool widely adopted across industries such as healthcare, manufacturing, and education. Minitab offers a range of statistical functions, including hypothesis testing, regression analysis, and ANOVA, along with various graphical tools that assist users in visualizing and interpreting data effectively.

WHAT IS MINITAB?

Statistics involves various techniques and tools for data analysis and inference, which are essential in any investigation [1]. While analysis can be done manually or with calculators, it is now commonly performed using statistical software like Minitab. Earlier versions of Minitab used a command-line interface, which, although effective and well-documented, made it challenging to use for teaching purposes [2]. The release of the Windows version made Minitab more user-friendly and popular in higher education. Its recent advanced versions, with enhanced features and graphical tools, have simplified the teaching and learning of statistics [3]. Over time, Minitab has evolved into a comprehensive system with extensive statistical tools, strong graphical capabilities, and well-organized support, leading to its widespread use in business, industry, and academia [4].

MINITAB is an effective, user-friendly statistical software program that offers a variety of fundamental and sophisticated data analysis features. Because of its simple command structure, MINITAB may be used by users with a wide range of skills and backgrounds. MINITAB is compatible with the majority of the top workstations, minicomputers, mainframes, and PCs and Macintoshes. The essence of MINITAB—the worksheet and commands—remain the same, despite variations across releases and computer platforms. Therefore, once you're familiar with using one version of MINITAB on a specific platform, transitioning to another version is simple. The Windows version of MINITAB features a user-friendly interface that makes statistical analysis accessible to users of all experience levels. With pull-down menus and dialog boxes guiding you through each step, getting started is as easy as double-clicking the program icon. MINITAB allows you to focus more on analyzing your data rather than spending time

instructing the software. Data can be entered directly into a spreadsheet-style window for convenience [5].

HOW MINITAB FACILITATES DATA ANALYSIS IN SIX SIGMA PROJECTS IN PHARMA INDUSTRY

Minitab plays a vital role in supporting data analysis within Six Sigma initiatives by offering a comprehensive suite of tools specifically designed to align with the DMAIC (Define, Measure, Analyze, Improve, Control) methodology. Here's how Minitab contributes to each stage of a Six Sigma project:

1. **Define Phase:** Minitab helps outline project objectives, scope, and key metrics by enabling users to gather and organize relevant data. It can be used to develop project charters and define clear goals. Additionally, it supports the creation of flowcharts and process maps, which help identify areas for potential improvement.
2. **Measure Phase:** During this phase, Minitab allows users to gather and analyze data to assess the current performance of a process. It streamlines data input, statistical computations, and the creation of visual tools like box plots and histograms. Its Measurement System Analysis (MSA) tools ensure the accuracy and consistency of data collection methods, which is essential in Six Sigma.
3. **Analyze Phase:** Minitab excels in this stage by providing a broad selection of statistical techniques. It facilitates hypothesis testing, regression analysis, and design of experiments (DOE), enabling users to identify root causes of problems and validate influential factors. Visual tools help reveal data patterns and relationships, making it easier to detect improvement opportunities.
4. **Improve Phase:** Minitab supports the implementation and evaluation of improvement strategies. It allows users to perform simulations, such as Monte Carlo analysis, to assess how various factors affect process outcomes. This phase also leverages tools like factorial design and response surface methodology (RSM) to optimize process changes.
5. **Control Phase:** In the final phase, Minitab helps establish and maintain control systems to ensure long-term success of improvements. Users can create and monitor control charts, define control limits, and track process stability. The software also aids in documenting procedures and producing visual materials for training and ongoing oversight.

MINITAB AND DMAIC

Minitab and DMAIC, two key components of the Six Sigma technique, collaborate to optimize processes and raise quality. As a statistical software program, Minitab fits in nicely with the five stages of the DMAIC architecture, which range from establishing project goals to managing and sustaining process enhancements. Six Sigma practitioners may make well-informed decisions at every level of the project because to its ability to streamline data collection, organize information, perform reliable statistical analysis, and aid in the visualization of data relationships. Minitab offers the tools and capabilities required to promote data-driven excellence in a Six Sigma setting, whether it is for hypothesis testing in the Analyze phase or the creation of control charts in the Control phase.

The integration of Minitab with the DMAIC methodology enables organizations to effectively uncover and resolve process inefficiencies, minimize defects, and improve overall quality. With its intuitive interface and robust statistical tools, Minitab simplifies the implementation of Six Sigma practices, making it an essential resource for professionals focused on process enhancement and ongoing improvement. Utilizing Minitab alongside DMAIC allows businesses to elevate quality standards, reduce process variability, and boost customer

satisfaction—factors that contribute significantly to greater competitiveness and long-term success in today's demanding market.

STATISTICAL ANALYSIS WITH MINITAB

Minitab's dynamic and adaptable statistical analysis process enables people and businesses to glean valuable insights from data. Users can easily run a variety of statistical studies thanks to Minitab's user-friendly interface, which streamlines the frequently complicated field of statistics. Minitab offers a full range of tools to meet various analytical needs, from organizing experiments and generating control charts to doing regression analysis and hypothesis testing. Furthermore, its capacity to produce lucid and captivating visuals improves the comprehension and dissemination of statistical outcomes. Minitab serves a broader purpose than mere statistical analysis; it promotes data-informed decision-making, reinforces quality control initiatives, and facilitates process improvement, ultimately leading to better results and enhanced efficiency across multiple sectors.

Professionals can use Minitab for statistical analysis to find trends, patterns, and make well-informed decisions based on data-driven evidence, regardless of their field—business, academia, healthcare, or manufacturing. Its extensive use in research, Six Sigma initiatives, quality control, and other fields highlights how useful it is as a tool for data analysis and decision support. Minitab continues to be a dependable and essential partner in a time when success depends more and more on data, making sure that the power of statistics is understandable and useful for both individuals and enterprises.

CREATING CONTROL CHARTS WITH MINITAB

Minitab control charts are an essential component of good quality control and process monitoring. Minitab's rich charting features and easy-to-use interface make it suitable for both novices and seasoned professionals. With only a few clicks, users of Minitab may quickly create a wide range of control charts, including p-charts for attribute data and X-bar and R charts for continuous data. The program plots data points, automatically determines control limits, and visually indicates any problems.

These control charts are equally easy to interpret; users may see patterns, changes, or anomalies that could point to process instability with ease. By offering a complete solution for monitoring and preserving control over crucial processes, Minitab enables firms to proactively solve quality concerns, lower errors, and improve process performance. Its function in making control chart development and interpretation easier guarantees that businesses can attain and maintain the greatest levels of efficiency and quality control, promoting ongoing operational improvement.

HYPOTHESIS TESTING IN MINITAB

The following are the basic steps to do hypothesis testing in Minitab:

1. *Data Entry*: Open Minitab and enter your data.
2. *Select Test*: From Minitab's menu, pick the precise hypothesis test you require (such as the t-test or ANOVA).
3. Clearly define your hypotheses by stating your alternative hypothesis (H_a) and null hypothesis (H_0).
4. *Run the Test*: Using your data, Minitab determines the test statistic and p-value.
5. *Interpret Results*: Dismiss the null hypothesis if the p-value is less than the significance level you have selected. Otherwise, don't reject it.
6. *Draw Conclusions*: Base your choices on the particular hypothesis test and the p-value.
7. *Produce Reports*: Utilize Minitab's features to generate reports and visualizations of your findings.

Minitab streamlines the process of hypothesis testing, making it easier to conduct and apply in data-driven decision-making across diverse industries.

REGRESSION ANALYSIS IN MINITAB

Regression analysis in Minitab is a valuable method for examining and measuring the relationships between variables. Its user-friendly interface allows users to conduct various types of regression, from basic linear models to advanced multiple regression analyses. To start, users input their data and select the response and predictor variables. Minitab then performs the analysis and delivers key statistics—such as coefficients, p-values, and R-squared values—that help evaluate the strength and importance of the relationships identified.

Access to result interpretation enables users to derive significant conclusions and forecasts from their data. Minitab's regression analysis features streamline the process, making it a vital tool for professionals in a variety of industries, whether they are determining the elements that influence sales numbers, assessing the success of marketing campaigns, or making well-informed research selections. Its usefulness is further increased by its capacity to visualize data and produce thorough reports, guaranteeing that businesses may use regression analysis to gain data-driven insights and make better decisions.

DESIGN OF EXPERIMENTS (DOE) MADE EASY WITH MINITAB

Design of Experiments (DOE) is a structured method used to optimize processes, enhance products, and determine key factors influencing outcomes. Minitab, a popular statistical software, streamlines the DOE process, making it user-friendly for both newcomers and experienced users. Here's how Minitab simplifies DOE:

1. **Experimental Design Wizard:** Minitab features a user-friendly wizard that walks users through each stage of setting up a DOE. It assists in selecting the right design, defining input factors and responses, and setting factor levels.
2. **Design Options:** Minitab offers a wide range of experimental designs, such as full factorial, fractional factorial, response surface, and mixture designs. Users can easily choose the most suitable design based on their experiment's goals and complexity.
3. **Factorial and Fractional Factorial Designs:** Minitab allocates factor values and automatically creates the required experimental runs according to the selected design. This saves time and money by streamlining the planning process and lowering the number of experimental experiments required.
4. **Response Optimization:** Minitab fits model and optimizes replies to assist users in analyzing the outcomes of their studies. It offers response surface plots, contour plots, and visualizations that help interpret the connections between responses and causes.
5. **Robust Parameter Design (RPD):** Minitab provides tools for performing robust parameter design, enabling users to optimize processes while accounting for variability and external noise, leading to more consistent and dependable results.
5. **Analysis of Variance (ANOVA):** Minitab streamlines ANOVA procedures, allowing users to easily pinpoint which factors and interactions have a significant impact on the experimental outcomes.
6. **Data Visualization:** Minitab's graphical features aid in the interpretation of results by enabling users to see how factors affect answers.
7. **Statistical Output:** The software produces thorough reports that condense the outcomes of the analysis, optimization, and experimental design, making it easy to share findings with stakeholders.

8. **Quality Improvement:** Because Minitab's DOE tools help practitioners determine the ideal process parameter settings that reduce variance and flaws, they are very useful in Six Sigma and quality improvement initiatives.

With its intuitive interface, automated computations, and robust analysis and reporting features, Minitab simplifies the design of experiments. This ease of use enables organizations to carry out experiments more efficiently and effectively, resulting in enhanced processes, better products, and higher overall quality—all while conserving time and resources.

USING MINITAB FOR ROOT CAUSE ANALYSIS

Minitab provides a full range of statistical tools and data analysis capabilities, making it a potentially in the root cause analysis process. The process starts with a precise problem definition and the collection of pertinent data, which Minitab assists in organizing and getting ready for analysis. Exploring data distributions and patterns is made easier by its user-friendly graphical tools and descriptive statistics, which offer important insights into the nature of the issue. Minitab proves highly valuable during the brainstorming phase by helping users create cause-and-effect diagrams to systematically explore potential causes across various categories. After identifying these causes, Minitab supports prioritization using Pareto analysis, allowing teams to focus on the most impactful factors first. It also enables data-driven validation of root causes through hypothesis testing and regression analysis, ensuring informed and accurate decision-making.

Beyond analysis, Minitab assists organizations in tracking the efficacy of solutions put into place, hence supporting corrective action planning and monitoring. Process stability and the actual mitigation of the identified root causes are guaranteed by control charts and continuous data analysis. Lastly, Minitab facilitates reporting and documentation, enabling businesses to efficiently convey results and take appropriate action while keeping an accurate record of the root cause analysis procedure. Minitab is essentially a vital tool for businesses dedicated to identifying the root causes of issues and putting data-driven solutions into practice for process and quality improvement [6].

5 WAYS MINITAB REAL-TIME SPC TRANSFORMS QUALITY MANAGEMENT IN PHARMA INDUSTRY

1. **Quick Identification of Process Deviations**

- Because of real-time monitoring, deviations or results that are not up to par are immediately noted.
- Lowers the possibility of creating batches that don't comply.
- Assures prompt action before flaws affect patient safety or product quality.

For instance, identifying a variation in tablet weight or coating thickness before it affects the entire batch.

2. **Automated Collection of data and Alerts**

- Pulls in data automatically and applies control rules (like Western Electric rules) in a seamless manner; connects with lab instruments, manufacturing equipment, and LIMS.
- Notifies users via SMS or email when a procedure is becoming unmanageable.

Impact: Shortens reaction times to important quality issues and minimizes human mistake.

3. **Data-Driven Decision Making**

Provides real-time dashboards and trend analysis.

Empowers QA/QC teams to make **informed decisions** based on current data rather than historical reports.

Supports **Continuous Process Verification (CPV)** as required by FDA/EMA.

Result: Enhances regulatory compliance and reduces risk of recalls or 483s.

4. **Consistent Observance of 21 CFR Part 11 and GMP**

- Guarantees safe data processing, audit trails, and electronic signatures.

From data entry until the final analysis or reporting, traceability is provided.

- Assists in keeping thorough records throughout regulatory examinations.

Benefit: Makes audit compliance and validation easier.

5. **Facilitates a Proactive Culture of Quality**

Proactive quality assurance replaces reactive quality control as the main focus.

Makes use of real-time information to promote a culture of continuous improvement.

- Promotes cooperation between engineering, QA, and production teams.

For instance, identifying training needs or equipment problems by trending OOS or OOT outcomes across shifts.

Minitab Real-Time SPC goes beyond being just a tool—it's a strategic asset for quality assurance. By delivering real-time insights, minimizing variability, improving process stability, optimizing equipment performance, and supporting predictive analytics, Real-Time SPC lays the foundation for a future where quality is not only sustained but consistently improved [7].

MINITAB IN PHARMACEUTICALS

Investigations started after producer Shire Pharmaceuticals found unwanted contaminants in therapies for uncommon diseases. Which was at fault, the process or the measurement system? Without knowing the reason, the contaminants ran the potential of causing issues with the product's release, such as noncompliance or compromising patient safety.

The foundation for successfully applying statistical tools to the various FDA Process Validation Guideline phases is provided by this pharmaceuticals track. Discover how to apply data analysis approaches to monitor the stability of a validated process, evaluate shelf life, comprehend product variation and flaws, and establish whether a process can satisfy specifications. The production of pharmaceutical medications, vaccines, test kits, and numerous other biological products for humans and animals depends on process validation. Three steps are suggested by the FDA for process validation. The statistical methods commonly used in each step of process validation can be applied to your data with Minitab's assistance [8]. Benefits of Data Analytics in pharmaceutical Companies given in Fig:1.

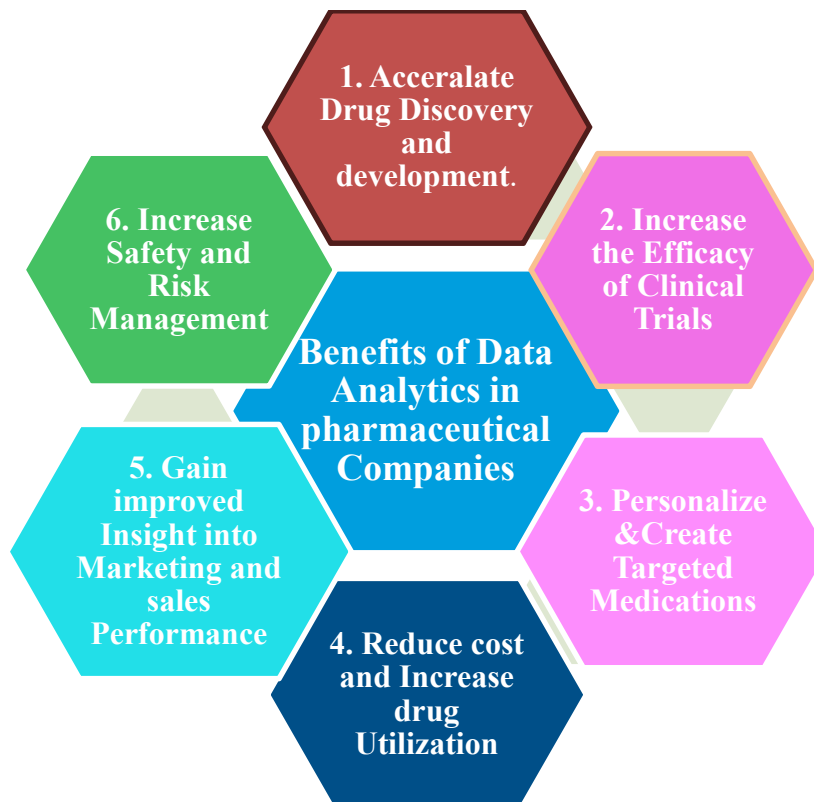


Fig. 1: Benefits of Data Analytics in pharmaceutical Companies

PROCESS CAPABILITY INDICES (PCI):

In the context of continuous quality improvement and Lean Six Sigma initiatives, Process Capability Indices (PCI) are fundamental tools. They serve as critical measures for assessing process performance and enable meaningful comparisons between different materials or suppliers. When correctly applied, they play a significant role in enhancing process control and efficiency.

The concept of Statistical Process Control (SPC), introduced by Walter Shewhart in 1939, offers a framework for evaluating quality and process variability in manufacturing. SPC identifies two main types of variation:

- Common cause variation: inherent and naturally occurring within the process.
- Special cause variation: arises due to specific, unusual events.

SPC implementation follows two phases:

- Phase I focuses on understanding the process and evaluating its stability.
- Phase II aims at identifying and eliminating sources of variation to maintain control.

Capability analysis applies primarily to stable processes, where performance is consistent over time. Variability the measure of consistency in product characteristics can be classified into:

- Instantaneous or natural variability, observed at a given moment.
- Long-term variability, observed over time.

This analysis often uses the Six Sigma range (natural tolerance or control limits) to assess how well a process performs.

As highlighted earlier, Process Capability Analysis is essential for any quality improvement strategy. It provides data that supports:

- * Predicting process compliance with specifications,
- * Supporting process development and modifications,
- * Setting appropriate sampling frequencies,

- * Defining equipment performance requirements,
- * Supplier selection,
- * Production planning under varying conditions,
- * Minimizing process variability.

Because of these advantages, statistical and capability analyses find applications across diverse fields, including design, offering a solid scientific basis for decision-making.

To evaluate process performance, tools such as Process Capability Indices (PCI), Process Performance Indices (PPI), and Process Sigma are commonly used. These analyses can be based on either historical records or newly gathered data. This particular study is based on the assumption that process output follows a normal distribution, as capability indices may yield misleading results with non-normal data. Process Capability Analysis allows for quantifying and monitoring variability in a process. By using capability indices, it assesses a process’s ability to stay within specification limits—essentially measuring the precision of the process. Several ratios and indices are available to calculate process capability, each offering a concise numerical evaluation of how well a process meets desired specifications. These insights help organizations identify improvement opportunities in both quality and performance. One of the most well-known indices is Cp, also known as the precision index. Cp measures the ratio between the specification width (difference between the Upper Specification Limit (USL) and Lower Specification Limit (LSL) and the process spread (represented by 6σ). It essentially expresses how well a process fits within the defined specification limit. [9]

ROLE OF PROCESS CAPABILITY IN PHARMACEUTICAL DEVELOPMENT:

According to **ICH Q10**, an essential goal in building a strong pharmaceutical quality system is to “**establish and maintain a state of control.**” This involves:

- Developing and implementing effective systems to **monitor and control both process performance and product quality**, and
- Ensuring that processes **remain suitable and capable over time**, providing consistent assurance of their ongoing release. [10]. Process capability reports given in Fig: 2, 3 &4.

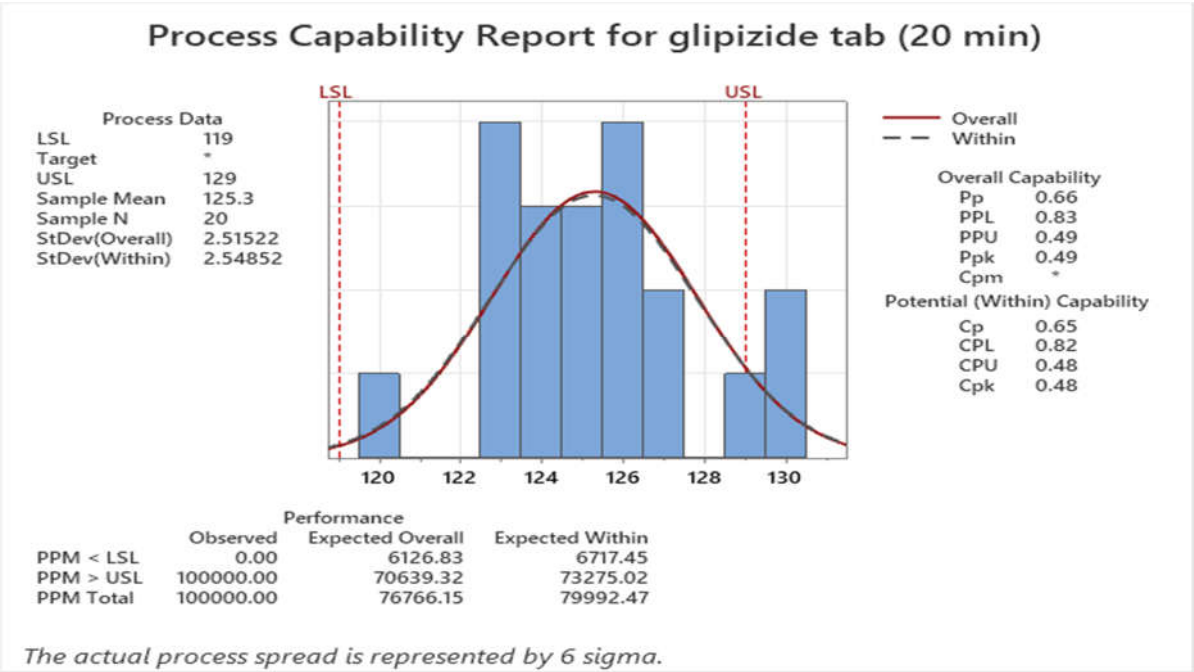


Fig. 2: Process Capability Report for glipizide tablets (20 min)

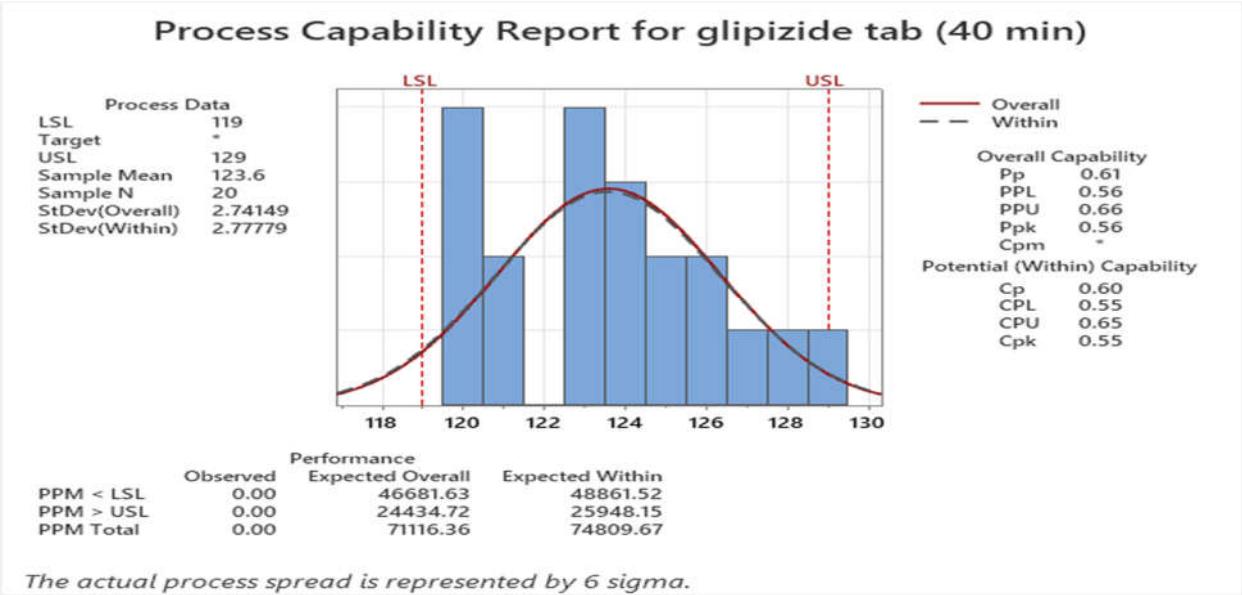


Fig. 3: Process Capability Report for glipizide tablets (40 min)

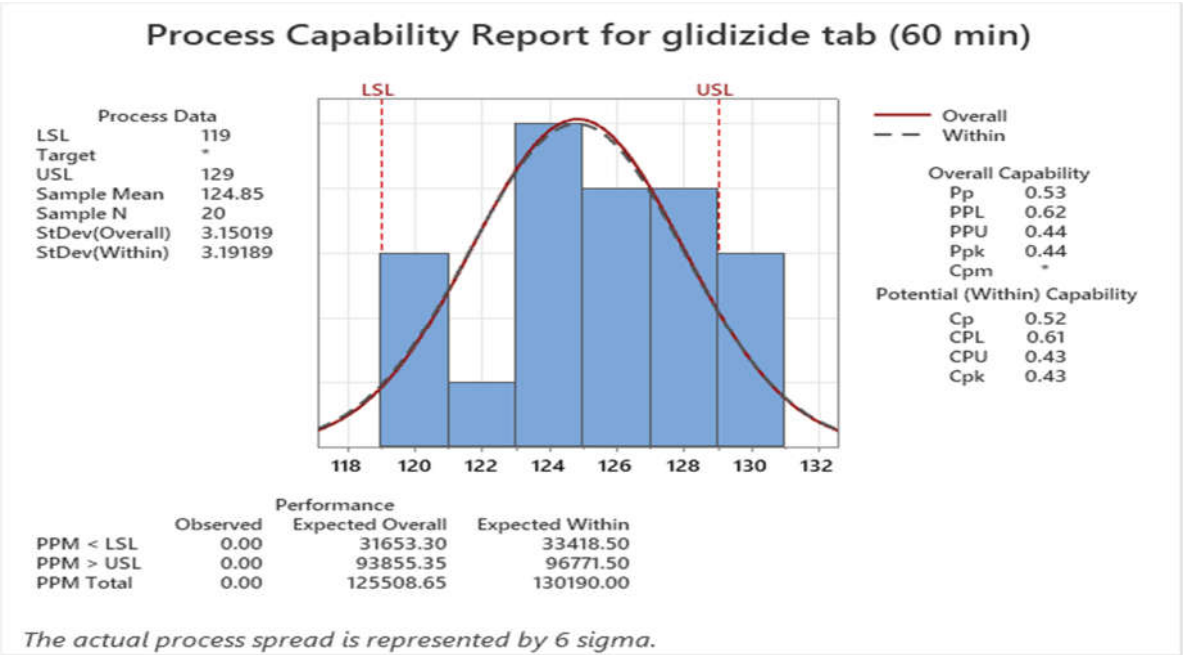


Fig. 4: Process Capability Report for glipizide tablets (60 min)

CONCLUSION:

Minitab plays a pivotal role in driving quality control, process improvement, and regulatory compliance across various industries, especially in the pharmaceutical sector where precision and consistency are critical. Its seamless integration with Six Sigma’s DMAIC framework empowers professionals to make informed, data-driven decisions at every stage of a project—from defining problems to implementing and sustaining improvements.

With its wide array of statistical tools, user-friendly interface, and specialized features like control charts, hypothesis testing, regression analysis, and Design of Experiments (DOE), Minitab enables users to uncover root causes, reduce process variability, and optimize performance. Minitab Real-Time SPC further enhances this by offering real-time monitoring, automated alerts, and compliance with regulatory standards such as 21 CFR Part 11 and GMP—critical for ensuring patient safety and product quality in the pharmaceutical industry.

Ultimately, Minitab is more than just statistical software; it is a comprehensive solution that supports a culture of continuous improvement. By simplifying complex analyses and offering

clear visualizations, it enables professionals at all levels to harness the power of data, enhance operational efficiency, ensure compliance, and achieve higher quality standards—making it an indispensable tool in today's data-driven landscape.

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CONFLICT OF INTREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CFR: Code of Federal Regulation; GMP: Good Manufacturing Practices; DOE: Design of Experiments.

ICH: International Community of Harmonization; FDA: Food and Drug Administration.

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