ENHANCING THE MANUFACTURING PRODUCTS' QUALITY USING STATISTICAL CONTROL CHARTS: A GOVERNANCE IMPLICATION

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Abstract

Control charts are essential tools for maintaining consistent quality and identifying variations in the production process, making them critical in industrial quality control (QC) (Wehrlé & Stamm, 1994; Eissa, 2018). This study addresses the limited adoption of statistical QC techniques at Avalon Pharma, a pharmaceutical company. It aims to assess the effectiveness of control charts (mean, standard deviation, and range charts) in improving the QC of Amaglime 2mg tablets. A sampling inspection plan was implemented, with subgroups of five tablets, and data were collected over 20 sample sets. The study finds that the application of statistical techniques enhances product quality by aligning inputs and outputs. However, Avalon Pharma currently lacks statistical QC methods and experts, and there is no consistent training program. The research recommends integrating scientific statistical inspection methods across all production stages, hiring statistical QC specialists, and offering regular training to improve process efficiency. This research contributes to understanding the role of statistical techniques in the pharmaceutical industry's QC systems and highlights the need for modernization in Avalon Pharma's practices.

Keywords: Quality Improvement, Statistical Process Control, Control Charts, Inspection

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1. INTRODUCTION

The majority of industrial companies increasingly rely on periodic inspection processes for their production operations to ensure the maintenance of the required level of quality and continuous improvement of these products. Improving product quality involves studying the behavior of the production process, which includes analyzing variations in specific data (production units during process operation). This statistical thinking enables us to understand and enhance the production process (Canavos & Miller, 1999). Understanding these variations in process outcomes over time, identifying their causes, and addressing them means tight control over process quality through statistical methods. This is achieved by selecting periodic random samples to detect changes in the process over time (based on differences observed between samples) through the use of quality control (QC)

charts. QC charts, regularly referred to as control charts, provide a strong and straightforward basis for assessing the stability of production process characteristics by tracking a specific statistical path on these charts. This involves monitoring stability in both the mean, standard deviation, and range in control charts. The configuration of QC charts depends on determining the size of the subgroups (periodic random samples selected from the production process) and the method of their selection. This is considered a crucial step in applying control charts, producing statistically significant values (Grant & Leavenworth, 1980; Al-Ashari, 2007).

QC charts are among the most important statistical tools in the field of QC and improvement. They elevate the level of decision-making in the production enterprise, providing accurate results and revealing the degree of deviations or differences in production processes and the reasons behind them. These charts allow for the comparison of product characteristics with adopted quality standards and measures. They contribute to identifying essential information that clarifies the causes of deviations in the production process, as well as the time and location of these deviations (Ibn Saeed, 1999). Understanding the reasons for deviations in a specific phenomenon over time, documented in graphical representations of statistical values, allows for the evaluation of the stability or instability of the production process. This enables adjustments and corrections to prevent the production of defective units (Al-Ashari, 2007).

The research problem of this study can be summarized as the limited adoption of modern scientific methods, particularly statistical techniques, in QC during the production process by many industrial companies. The research specifically aims to address this issue within Avalon Pharma, a pharmaceutical company. The goal is to elevate the effectiveness of its control system to ensure the quality of its products. The primary objective of this research is to explore the QC techniques implemented by Avalon Pharma, the pharmaceutical company, and evaluate their effectiveness in strengthening the control process. This involves aligning the company with modern scientific techniques and providing it with a scientific framework, utilizing statistical control charts. The aim is to address and resolve the challenges faced in the QC of its products and work towards enhancing them. The significance of this research stems from the fact that many of our Arab industries are relatively new and face strong competition from foreign products, often due to lower quality. Therefore, these companies must focus on developing, improving, and controlling the quality of their goods, particularly since the product is directly linked to the health and safety of the consumer (pharmaceutical products). This research, specifically conducted within Avalon Pharma, aims to reinforce the company with statistical techniques that assist in competing effectively, ensuring consumer satisfaction, and maintaining a high standard of product quality.

The structure of this paper is as follows. Section 2 provides a literature review on statistical QC, the application of control charts in industrial settings, and hypotheses development. Section 3 outlines the research methodology, explaining the statistical techniques used, including the design of control charts and sampling methods. Section 4 presents the results and discusses the findings regarding the effectiveness of the control charts in improving the QC at Avalon Pharma. Section 5 concludes with recommendations for enhancing the QC process and suggestions for future research.

2. LITERATURE REVIEW AND HYPOTHESES DEVELOPMENT

The related reviewed studies collectively shed light on the application and impact of statistical control in diverse industrial contexts.

Ajadi et al. (2025) presented two robust multivariate Shewhart-type control charts for detecting changes in the covariance matrix, focusing on sulfur dioxide monitoring in QC. The method utilizes the least absolute shrinkage and selection operator (LASSO) for penalization and singular value decomposition (SVD) of the shrunken covariance matrix to ensure robustness against non-normality. Performance comparisons show superior robustness to normality assumptions compared to existing methods. While computational complexity may limit scalability for large datasets, the approach effectively analyzes multivariate chemical data, as demonstrated in white wine production, improving QC in non-normal environments.

Al-Tahan (2024) discussed the importance of control charts in pharmaceutical manufacturing as a key tool for statistical process control (SPC). The study highlights the use of control charts to track variations in production processes, ensuring that these variations remain within acceptable limits. By doing so, control charts contribute significantly to maintaining consistent product quality and process stability in pharmaceutical operations.

The study by Ample Logic (2024) emphasizes the role of SPC in improving pharmaceutical quality assurance. By employing control charts such as X-bar and R-charts, the study demonstrates how SPC can effectively monitor the stability of production processes. It underscores the ability of control charts to detect variations, identify potential problems, and ensure that products meet the required quality standards consistently, thereby enhancing the overall manufacturing process.

Smajdorová and Noskievičová (2022) emphasized the potential of nonparametric control charts (NPCC) in monitoring processes within the context of smart manufacturing, characterized by complex structures, diverse monitored characteristics, and the need to handle large datasets. Despite this potential, practical applications of NPCCs are infrequent due to a lack of software support and clear application instructions. The authors aimed to address this gap by introducing a manual based on their simulations of NPCC performance under various violations of data prerequisites. The paper covers a broad range of control charts and assesses their effectiveness in diverse practical situations. The study also evaluates performance indicators such as average run length (ARL), median run length (MRL), X5, and X95 through simulations to identify the most suitable NPCC. The methodology was validated using real data.

Eissa (2018) conducted a retrospective study on the manufacturing quality of pharmaceutical product batches by monitoring assay results and trends for three active ingredients: Paracetamol (Pa), Chlorpheniramine Maleate (CM), and Pseudoephedrine Hydrochloride (PH). The study employed two types of control charts, individual-moving range and Laney

U chart, to assess in-process monitoring. Analysis revealed that CM's relative potency was significantly higher than Pa and PH. Capability analysis showed that Pa and PH assays met the required specifications, while CM potency failed to stay within the specified window level, indicating a significant shift outside the upper limit. Both types of control charts had the same limits, but the individual-moving range chart proved more sensitive in detecting out-of-control states.

Woodall et al. (2004) conducted a study on the use of control charts for monitoring process and product quality profiles. They reviewed existing literature on SPC and connected the use of control charts to functional data analysis. The authors explored applications in linear and nonlinear profiles, as well as the use of splines and wavelets. They expressed a strong interest in advancing research in profile monitoring and suggested potential directions for future studies.

Guo et al. (2008) explored the construction of QC charts in a random fuzzy environment based on the principles of axiomatic credibility measure theory. They highlighted that the global business environment accelerates product life cycles, leading to challenges such as diversification in product designs, raw material supply, and intermediate part manufacturing to final commercial goods. These challenges involve multinational companies, introducing vagueness and randomness into manufacturing processes. The coexistence of randomness and fuzziness in modern manufacturing necessitates adjustments to QC methodologies to achieve high customer satisfaction and enhance market share.

Rasheed (2020) applied time series methods, specifically relying on the simple moving average model and simple exponential smoothing model, to construct QC charts for moving averages and exponentially weighted moving averages. The data utilized was from the General Battery Industry Establishment in 2014. The study concluded that using an exponentially weighted moving averages chart for controlling abnormal time series is more effective than employing a moving averages chart. Rasheed (2020) emphasized that maintaining control over the production process is crucial for production companies to analyze their status, achieve high-quality production with acceptable specifications, and contribute to the overall development of industrial companies.

Zheng (1995) highlighted the significance of QC and control charts for low-volume manufacturing, which constitutes more than 50% of overall manufacturing. While control charts, a statistical method, are typically effective for long and continuous runs of the same product in a specific process, they encounter challenges in low-volume manufacturing where various parts are produced in small quantities. The paper introduces three methods to address this issue. These methods involve special transformations that allow operators to plot multiple part numbers on the same chart by converting data from different part numbers to a common distribution. The three methods presented are the universal chart method, the relative tolerance method, and the fixed sample size method.

Kammoun et al. (2023) introduced a novel integrated strategy for a manufacturing system facing random failures and producing both conforming and non-conforming products. The manufacturing unit's degradation, influenced by production rate and usage time, impacts both reliability and product quality. The proposed joint policy aims to optimize production planning over a finite horizon to meet random demand under a specified service level. Simultaneously, it seeks to determine the optimal frequency of imperfect preventive maintenance actions per production cycle and set optimal parameters for a control chart to monitor quality effectively in the presence of assignable causes. Additionally, the proposal includes a rework process for a portion of the non-conforming products identified with assignable causes, aiming to enhance their quality for resale as second-rate products. The optimization model considers various costs, such as production, reworking, storage, rejection, quality, and maintenance, with the objective of minimizing average total costs. The study provides numerical examples and sensitivity analyses to demonstrate the efficacy of the proposed integrated approach.

Nasiri and Darestani (2016) emphasized the importance of employing QC tools to ensure product and service quality in organizations. Recognizing that precise data may not always be available, they highlighted the suitability of fuzzy sets theory for modeling processes where observed data are vague. The researchers specifically focused on fuzzy control charts designed to handle uncertainty arising from fuzziness. In this study, the authors conducted a literature review covering the period from 1990 to 2012, examining the fuzzy application of control charts. The analysis considered various aspects such as publication year, journal title, author's affiliation, data source, fuzzy theory classification, control chart classification, and research location. The findings revealed a positive and increasing trend in research activities in the last decade. In conclusion, the study suggested that further investigations are needed in the application of fuzzy set theory to control charts, particularly in areas such as performance criteria, membership, distribution function, heuristic methods, and attribute control charts.

Gunay and Kula (2016) investigated a two-stage stochastic programming model for determining control limits in P-charts when a production process surpasses a specified quantity. They emphasized the importance of considering production quantity in control limit determination to balance the challenges associated with wider limits, leading to difficulty in detecting process changes, and narrower limits resulting in unnecessary interventions and higher inspection costs. Applying their model to an automotive manufacturing scenario, specifically focusing on paint defects in cars, the study formulated the problem as a two-stage stochastic programming model. In the first stage, the control limit parameter k for the P-chart was determined, and in the second stage, production quantity was optimized to minimize total quality-related and production costs. The model was solved using a sample average approximation (SAA) algorithm. The numerical study showed that an increase in the mean defect rate led to higher total cost and total production quantity. The impact of an increasing process variance on the control limit parameter k was relatively small. The frequency of special cause occurrences significantly affected total cost, and the experiments suggested that commonly used 3r control limits in practice are wider than necessary.

Ertuğrul and Aytaç (2009) aimed to integrate SPC with fuzzy set theory, leveraging statistical techniques to monitor and control product quality. Control charts, commonly used for monitoring manufacturing processes, were employed in this study. Fuzzy sets and fuzzy logic, recognized as potent tools for modeling uncertain systems in various domains, were incorporated into the textile industry for monitoring yarn quality. The control charts proposed were constructed based on fuzzy theory, considering quality in terms of grades of conformance rather than absolute conformance and nonconformance. The study also constructed control charts based on probability theory using the same data for a textile company. The comparison of results from the two approaches revealed that fuzzy theory outperformed probability theory in effectively monitoring product quality.

Islam and Islam (2017) demonstrated the application of various statistical QC tools to achieve continuous quality improvement in the context of a ready-made garments (RMG) manufacturing factory. The study utilized variable control charts and attribute control charts, developed using "Minitab 17", to analyze the process output of the factory. The control charts were employed to assess the current stability of the manufacturing process. Subsequently, the Deming model, often referred to as the PDCA (Plan-Do-Check-Act) cycle, was employed to identify and select opportunities for enhancing QC. The PDCA cycle was tailored to the existing state of the process and the rate of defective products, involving management personnel in its generation. The findings indicated that the process was not stable during the study period. The PDCA cycle model included proposals for further improving the manufacturing process.

Al-Ashari (2007) focused on statistical sampling techniques in Yemeni pharmaceutical companies, revealing a deficiency in the application of these techniques, negatively impacting competitiveness. Almasani (2004) highlighted the positive influence of statistical control on cement production quality in Yemen. Al-Zamki's (2003) study emphasized the effectiveness of QC boards and statistical methods in a Yemeni company for mills and grain silos.

Wehrlé and Stamm (1994) highlighted the significance of statistical input in QC due to the inherent uniqueness of each manufactured unit. While statistical control may be unnecessary in an ideal scenario of perfect batch replication, real-world manufacturing involves factors contributing to unit uniqueness, necessitating statistical control. The authors advocated for using control charts to efficiently detect and eliminate nonrandom causes of variation. Once a manufacturing process is under statistical control, capability studies assess its compliance with specifications. A stable and highly capable process allows for the application of optimization methods to enhance product characteristics. Employing multifactorial analyses, the authors revealed fundamental data structures, especially when dealing with numerous variables across multiple items. They emphasized that achieving excellence in QC requires a continuous, gradual accumulation of knowledge about the manufacturing process over time, rather than relying on a single method or a one-time approach.

Al-Areqi's (2000) research indicated that while the production process at Al-Barh Cement Factory is under statistical QC, issues persist in the packaging process. Al-Sarn's (2000) study stressed the importance of statistical QC in Syrian industrial companies, emphasizing benefits such as specialized staff training and the development of a quality culture. Bishmani's (2000) investigation in Syrian companies revealed challenges such as the absence of a centralized QC authority and limited application of statistical techniques, leading to defective products. Overall, these studies underscore the growing importance of statistical control in maintaining product quality, highlighting common challenges like the lack of technique application, insufficient training, and the need for a quality-focused organizational culture. Recommendations consistently advocate for the adoption of statistical methods, training programs, and a systematic approach to QC, contributing valuable insights into the pursuit of effective quality management.

Based on the above discussions, this study predicts the following direct hypotheses:

H1: The methods used in quality control of Avalon Pharma's products are entirely distinct from the statistical techniques employed in this study.

H2: The proper application of statistical techniques works to enhance the efficiency and effectiveness of quality control.

H3: Deviating from defined quality standards and specifications shifts consumer preferences towards competing products with higher quality.

3. RESEARCH METHODOLOGY

3.1. Approaches used

This study adopted the following methodologies to achieve the objectives of the study:

1. Deductive approach: This involved a theoretical study based on a review of statistical literature related to statistical techniques and methods of QC. The researchers employed recent academic contributions from books, previous studies, Arabic and foreign journals, publications, and other official documents available from the company.

2. Inductive approach: This was implemented through an empirical study utilizing data on the actual production process. The researchers studied and analyzed this reality, observed the industrial process at all production stages, and conducted direct inspections by random sampling (subgroups). This approach aimed to infer product quality and achieve the research objectives. Personal interviews were also conducted with individuals involved in QC at the company.

3.2. Sample, inspection and quality control charts

Inspection is considered one of the fundamental pillars of a QC system. It is a crucial element in the evaluation and control process of this system, aiming to distinguish between products that conform to specifications and those that do not, as well as to detect any changes in the production process.

QC charts are used to measure the quality of products during the production process and compare product characteristics with adopted standards and specifications to assess quality. These charts are a method that contributes to identifying fundamental information illustrating the causes of

deviations in the production process, including the time and location of these deviations (Ibn Saeed, 1999).

3.2.1. Charts X-bar

The most likely scenario in practical reality is the difficulty in understanding the characteristics of the production process. This prompts us to estimate the QC limits for control charts and their central line for control (CLC). According to the pioneering work of the world-renowned expert in control charts, Shewhart (1923), explained that selected samples can reflect variations in the outputs of the production process. This is achieved by using at least 20 samples, each with a size of five or 10 units at any given time, to ensure the accuracy of changes, especially when dealing with standard deviations. In other words, choosing a small sample size allows us to study the quality characteristic over frequent intervals rather than selecting many units over shorter periods. This justifies the use of rational subgrouping. Some prefer choosing 15 samples or more with a size of 5–4 units. To determine the upper (UCL) and lower (LCL) control limits and the CLC, we need to calculate the mean and the standard deviation statistically. Therefore, we find that $E(X) = \mu$, which means that x is an unbiased estimate of, and, therefore, x represents the center line of the panel in this case.

Given that the control limits depend on the value of σ for the community, which is often unknown in QC communities, it is estimated from the average standard deviation of a group of samples taken from the output of the production process (the partial group), or it is estimated from the average range (R bar) for a group of samples taken. Also, from the output of the production process, and in practice, the calculations are simplified by using the product of multiplying the mean of the range by the factor (A2) to replace the three standard deviations. That is, A2 is fixed to convert the average range into three standard deviations of the distribution of means, and this factor (A2) changes with the sample size and is given in special tables.

That is:

$$A_2\overline{R} = 3\sigma_{\overline{x}} \tag{1}$$

where,

$$\sigma_{\overline{x}} = \frac{\sigma}{\sqrt{n}} \tag{2}$$

The estimate σ is d_2, where d_2 is a coefficient for the sample size. That is:

$$3\sigma_{\overline{x}} = \frac{3\sigma}{\sqrt{n}} = \frac{3}{d_2\sqrt{n}} . \overline{R} \tag{3}$$

$$A_2 = \frac{3}{d_2\sqrt{n}} \tag{4}$$

$$3\sigma_{\overline{x}} = A_2\overline{R} \tag{5}$$

Therefore, the upper and lower limits of the control panel are:

$$UCL = \bar{\bar{x}} + A_2\overline{R} \tag{6}$$

$$LCL = \bar{\bar{x}} - A_2\overline{R} \tag{7}$$

3.2.2. Chart S

We choose the subsets of size n, for which $m \geq 20$ samples, and calculate the S statistic representing the mean and standard deviations of the samples or subsets as follows:

$$\overline{S} = \frac{1}{m}\sum_{i=1}^{m} S_i \tag{8}$$

In order to determine the UCL and LCL and the CLC, we must determine the arithmetic mean and the standard error of the S statistic, and accordingly, we find that: S represents the center line of the panel in this case, and since the standard deviation of the sample (i) is S_i, and $E(Si) = C4\sigma$, and through m subsets we find that the expected value of the statistic S is:

$$E(\overline{S}) = C_4\sigma \tag{9}$$

$$UCL = \overline{S} + 3(C_5\frac{\overline{S}}{C_4}) \tag{10}$$

$$LCL = \overline{S} - 3(C_5\frac{\overline{S}}{C_4}) \tag{11}$$

When using S and X-bar, the appropriate formulas used in calculating the CLC and the adjustment limits are:

$$\overline{S} = \frac{1}{m}\sum_{i=1}^{m} S_i \tag{12}$$

$$\bar{\bar{x}} = \frac{1}{m}\sum_{i=1}^{m} x_i \tag{13}$$

$$UCL_{\overline{x}} = \bar{\bar{x}} + A_3\overline{S} \tag{14}$$

$$UCL_S = B_4\overline{S} \tag{15}$$

$$LCL_{\overline{x}} = \bar{\bar{x}} - A_3\overline{S} \tag{16}$$

$$LCL_S = B_3\overline{S} \tag{17}$$

Finally, it can be said that most industrial processes do not fall within the control limits when analyzed for the first time. In these cases, we neglect the points outside the control limits, and the new control limits are calculated. In the case of plate and S, the new control limits are given as follows:

$$LCL_{\overline{x}} = \bar{\bar{x}}_{new} - A\frac{\overline{S}_{new}}{C_4} \tag{18}$$

$$LCL_S = B_5\frac{\overline{S}_{new}}{C_4} \tag{19}$$

$$CL_{\overline{x}} = \bar{\bar{x}}_{new} = \frac{\sum\overline{x} - \sum\overline{x}_r}{m - m_r} \tag{20}$$

$$CL_S = \overline{S}_{new} = \frac{\sum S - S_d}{m - m_d} \quad (21)$$

$$UCL_{\overline{x}} = \overline{\overline{x}}_{new} + A\frac{\overline{S}_{new}}{C_4} \quad (22)$$

$$UCL_S = B_6\frac{\overline{S}_{new}}{C_4} \quad (23)$$

where, *CL* — central limit.

4. RESULTS AND DISCUSSIONS

The following elements show the preview plan for implementing variable control panels (S, X):

- Process: Thickening Amaglime 2 mg tablet.
- Subgroup size: Five discs, selected sequentially.
- Number of partial groups: 20 partial sets (sample).
- Preview course: One sample of 7 minutes, within half an hour of production.

Operating specifications of Thickening Amaglime 2 mg tablet:

1) CLC = 3.1mg.
2) LCL = 2.85mg.
3) UCL = 3.25mg.

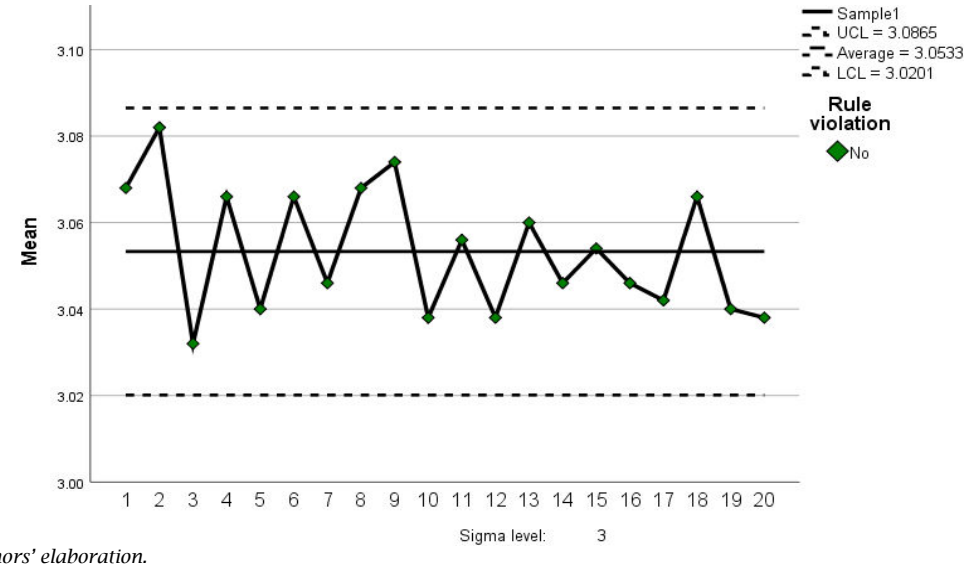
According to the previous inspection plan, the adjustment panels (S, X-bar) were applied to the current state of operation, and the adjustment limits for each panel were calculated. The results of the application are shown in the following table, which shows the data of the adjustment panels (S, X-bar) for the thickness of the tablets. Table 1 shows that the middle line of the panel was calculated.

X-bar, S, R, UCL, and LCL adjustment limits of the panel were calculated, and the X-bar panel, S, and R were drawn as follows in the figures below.

Table 1. The data of the control panels (S, X-bar, R) for the thickness of tablets

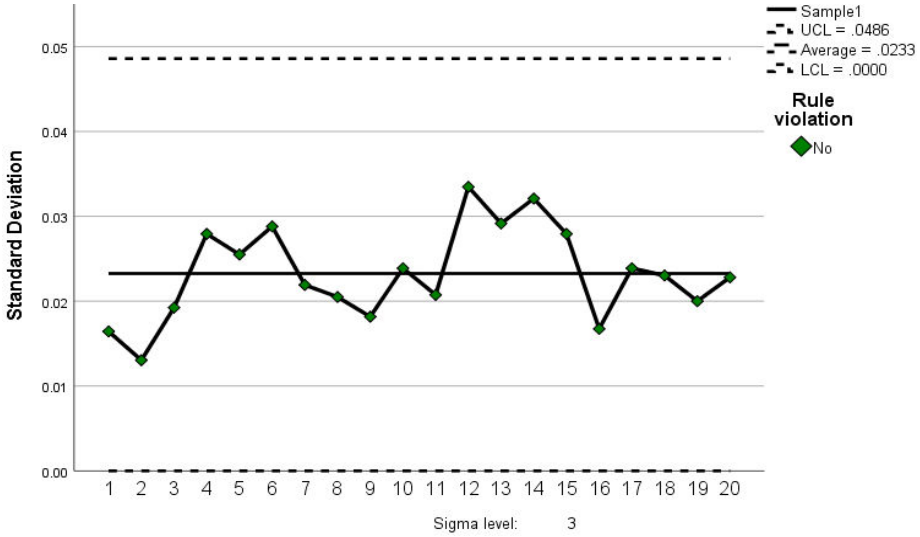
Sample No.	*Sample 1*	*Sample 2*	*Sample 3*	*Sample 4*	*Sample 5*	*X-bar*	*S*	*R*
1	3.06	3.09	3.06	3.05	3.08	3.07	0.02	0.04
2	3.09	3.06	3.09	3.08	3.09	3.08	0.01	0.03
3	3.04	3.03	3.01	3.02	3.06	3.03	0.02	0.05
4	3.06	3.1	3.04	3.04	3.09	3.07	0.03	0.06
5	3.02	3.01	3.06	3.04	3.07	3.04	0.03	0.06
6	3.09	3.09	3.07	3.06	3.02	3.07	0.03	0.07
7	3.04	3.04	3.02	3.08	3.05	3.05	0.03	0.06
8	3.09	3.05	3.06	3.05	3.09	3.07	0.02	0.04
9	3.05	3.08	3.06	3.09	3.09	3.07	0.01	0.03
10	3.02	3.04	3.07	3.01	3.05	3.04	0.03	0.06
11	3.07	3.04	3.03	3.06	3.08	3.06	0.02	0.05
12	3.01	3.05	3.03	3.09	3.01	3.04	0.03	0.08
13	3.07	3.02	3.09	3.04	3.08	3.06	0.03	0.07
14	3.09	3.07	3.03	3.02	3.02	3.05	0.02	0.05
15	3.06	3.04	3.1	3.03	3.04	3.05	0.03	0.07
16	3.06	3.02	3.06	3.05	3.04	3.05	0.02	0.04
17	3.07	3.06	3.04	3.01	3.03	3.04	0.02	0.05
18	3.09	3.07	3.08	3.06	3.03	3.07	0.02	0.05
19	3.02	3.07	3.03	3.05	3.03	3.04	0.02	0.04
20	3.06	3.04	3.01	3.06	3.02	3.04	0.02	0.05
Total						3.05	0.02	0.05

Figure 1. Control chart: Sample 1 — Mean



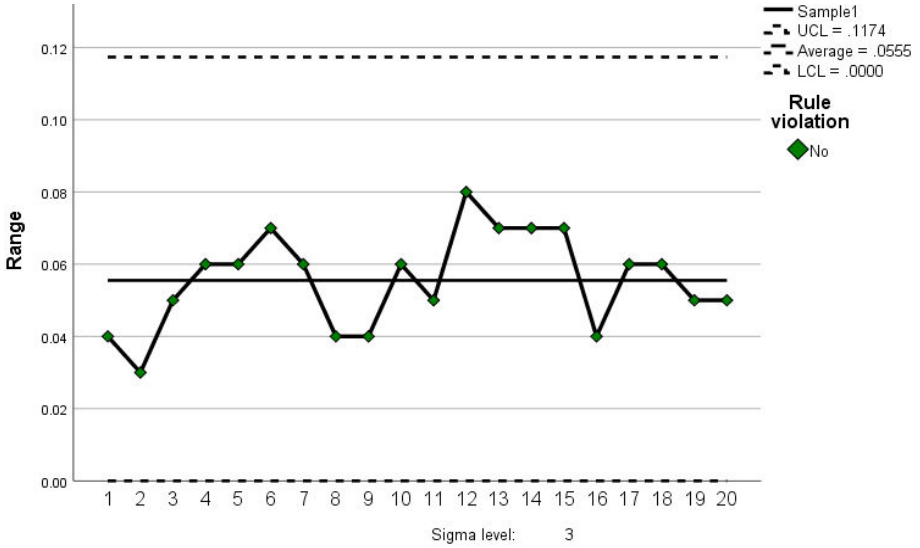
Source: Authors' elaboration.

Figure 2. Control chart: Sample 1 — Standard deviation



Source: Authors' elaboration.

Figure 3. Control chart: Sample 1 — Range



Source: Authors' elaboration.

The application of statistical control charts (S, X-bar, R) to Avalon Pharma's production process, particularly focusing on the thickness of Amaglime 2 mg tablets, has provided important insights into the QC of the manufacturing process. The results from the control charts indicate that there are no values of X-bar, S, or R outside their control limits. This suggests that the production process remained stable during this period, with no unusual causes affecting the process. Since the sub-sample size was set at 5 ($m = 20$), the stability of the production process was ensured for the average of the Thickening Amaglime 2 mg tablets. Therefore, it is concluded that the same control limits will apply to future samples, assuming similar conditions.

However, the absence of values outside the control limits does not necessarily guarantee compliance with the product's specified requirements. Process stability is distinct from the process capability to meet product specifications. This distinction will be further explored in future research focusing on process capability analysis. In this study, eight tests were conducted using the SPSS program, and the analysis confirmed the stability of the process, with no distinguishable pattern emerging over time. This indicates that the process is functioning under normal operating conditions and is stable within the defined parameters. It is important to highlight that the stability of the process does not necessarily equate to meeting product specifications. Therefore, while the control charts indicate that the process is stable, further investigation into process capability is necessary to ensure that the product consistently meets the required quality standards. This aspect will be addressed in future research.

The findings from this study are significant in the broader context of industrial QC. The proper application of statistical QC techniques, such as control charts, ensures continuous improvement in product quality by identifying variations in the production process. This is particularly important in industries like pharmaceuticals, where product consistency is critical for consumer safety.

The results of this study suggest that Avalon Pharma, despite having stable processes, lacks the integration of statistical techniques into its QC practices. Furthermore, there is a noticeable gap in the presence of specialists in statistical QC and the lack of regular training programs in this area.

These findings have implications not only for Avalon Pharma but also for the pharmaceutical industry as a whole. The absence of statistical QC methods is a common challenge in industries where traditional inspection methods dominate. The study underscores the necessity of adopting scientific statistical inspection techniques at all stages of production to enhance product quality. The application of these techniques, as evidenced by the findings, improves the efficiency and effectiveness of QC. In broader industries, such as pharmaceuticals, statistical methods like control charts are crucial for maintaining quality and competitiveness, especially in markets with stringent regulations and high consumer expectations. The research findings align with industry practices in global pharmaceutical companies, where similar control charts are utilized to maintain batch consistency and ensure that the production process remains stable, even when there are fluctuations in input materials or production conditions.

Additionally, the findings emphasize the need for companies to recruit statistical QC professionals and integrate them into departments responsible for quality assurance. This is essential not only for process stabilization but also for optimizing production efficiency. Furthermore, regular training programs in statistical QC are vital for enhancing the capabilities of the workforce and ensuring long-term process improvement.

The study confirms that the use of statistical control charts in the production process of Amaglime 2 mg tablets can significantly improve QC. The process is stable, but further investigation into process capability is necessary to ensure that product specifications are consistently met. This study recommends the adoption of scientific statistical inspection techniques, the recruitment of statistical experts, and the implementation of specialized training programs in QC. These recommendations are essential for enhancing the effectiveness of QC systems, particularly in the pharmaceutical industry, where product quality and safety are paramount.

5. CONCLUSION

The primary objective of this research was to evaluate and assess the effectiveness of statistical QC methods employed at Avalon Pharma, a pharmaceutical company, focusing on their production processes. Specifically, the study highlighted the use of QC charts such as the mean chart (X-bar), standard deviation chart (S), and range chart (R), which were found to be effective tools for enhancing the consistency and quality of the production process. The results indicate that the proper application of these statistical methods led to continuous improvements, ensuring a stable process with minimal variations, and guaranteeing a better alignment between inputs and outputs. One of the most important findings of the study is the improvement in the efficiency and effectiveness of the QC procedures through the use of statistical inspection methods. However, the research also revealed a critical gap within Avalon Pharma, as the company currently does not utilize statistical techniques for QC and lacks personnel specialized in statistical QC. Additionally, there is an absence of regular, specialized training programs in this area. This limitation undermines the potential benefits that such methods could offer in maintaining and improving product quality.

The implications of this study extend beyond Avalon Pharma and can be applied to various industries. In the broader context of industrial manufacturing, the adoption of statistical QC techniques such as control charts is crucial for ensuring product consistency and quality. Industries like automotive, food production, and electronics can significantly benefit from the use of statistical methods to monitor and improve their production processes. The ability to detect process deviations early and take corrective actions minimizes waste, enhances productivity, and ensures compliance with quality standards. Moreover, adopting these methods can be a competitive advantage in global markets where quality and consistency are of paramount importance.

In industries like pharmaceuticals, where product quality directly impacts consumer health and safety, the implementation of scientific statistical techniques is critical for meeting regulatory standards and ensuring consumer trust. The results of this study underscore the importance of integrating statistical QC methods into production processes across various sectors to minimize defects, reduce production costs, and maintain high levels of product quality. Furthermore, the research suggests that other industries, especially those involved in high-precision manufacturing, should invest in hiring experts in statistical QC and provide regular training to their workforce. This will help in fostering a culture of continuous improvement, which is vital for maintaining competitive advantages in a rapidly evolving marketplace. The integration of these practices also aligns with the growing trend toward data-driven decision-making in industries worldwide.

While the findings of this research are promising, it is important to note that this study was limited to Avalon Pharma. Future research could expand the scope by considering other pharmaceutical companies, such as Pfizer, Sanofi, Novartis, Tabuk, SPIMACO, and AstraZeneca, to further validate the applicability of statistical QC techniques in the pharmaceutical sector. Moreover, conducting similar studies in other regions, such as the GCC countries (Qatar, Oman, Kuwait, Bahrain, and UAE), could provide a more comprehensive understanding of the challenges and opportunities for implementing these techniques in different cultural and economic contexts. This study primarily examined the use of X-bar and S-charts. Future research could explore the application of additional QC charts, such as P-charts, moving range (MR)-charts, and U-charts, to assess their utility in different production environments. By doing so, future studies can offer a more complete picture of the most effective statistical tools for QC across various industries.

This paper highlights the critical role of statistical QC methods in enhancing the efficiency and stability of production processes, ensuring

consistent product quality, and reducing waste. The practical implications of this study are significant for not only the pharmaceutical industry but also for other industries where QC is essential. As industries continue to evolve and face increasing global competition, the adoption of scientific and statistical approaches to QC will be crucial for maintaining operational efficiency, meeting regulatory requirements, and ensuring the satisfaction of consumers.

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