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Process Performance Analysis in the Production Process of Medical Bottles

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Abstract:
The importance of the quality in creating customer satisfactionhas been widely studied in the literature. Product quality relates to how well the product characteristics fulfill the customer expectations. Since, maintaining a competitive advantage in the market highly depend on the customer satisfaction, manufacturer needs to reduce the production variability to produce quality products. Statistical quality control (SPC) applications are performed in the manufacturing industry to measure the performance of the production performance. Process capability analyze is an effective method to evaluate the process performance. Process capability indices (PCIs) are used to quantify the relationship between the real process performance and the predefined specification limits. PCIs are statistical indicators of the process capability. In this study, process capability analysis is conducted in a medical bottle manufacturing company. Process performance measurement gains great importance in health industry as it has a critical role. The company determines the critical quality characteristics of the medical bottle as weight, thickness, height and diameter.

Keywords: *Process capability, gage management, quality control, pharmaceutical industry, control diagrams.*

1. Introduction

Quality is defined as the ability to respond to customer requirements. But customer satisfaction alone is not sufficient; it is important to maintain and improve after achieving the quality. Sustainable product quality will be possible to work based on a systematic and scientific basis. Statistical quality control is a concept encountered in this step including systematic and scientific techniques. Accepting sampling, control charts and process capability analysis are statistical tools used in quality control. The process capability analysis is the topic discussed in this study. Production processes always show variation in their product's characteristics. This variation arises two types of cause: assignable and natural causes. All of the statistical quality tools aim to detect and eliminate the assignable variation in the process. Capability analysis can be applied to a process eliminated from assignable causes. In other words, the process can only be under the influence of natural causes.

The process capability is a statistical calculation performed on a data set to determine the adequacy of the system discussed. Measurement of a process capability is to know how well the process will meet specifications and level of control necessity. Process capability expresses also the ability of the integration of machine, material people, and methods to obtain a product that will regularly meet customer requirements and engineering specifications. The study of a process capability is carried out to find an answer the question of "Does the process need to be improved?" There are three steps for making a process capability working; the study of planning, collection of the data, and analyzing of the data. The techniques used for the process capability analysis are histograms; probability plots, control charts, and experiments design (Montgomery, 2001). Control charts are one of the simple and effective process monitoring and process capability analysis methods. Control charts are used to determine whether a process operates under in control or not. Before analyzing the process capability, must be sure that the process is statistically in control condition. Process capability indices are only significant for processes in control condition. Process capability is identified by capability indexes. Process capability indexes measure the ability of process to meet engineering tolerances or limits. The most common capability indexes used in the literature are C_p, C_{pk}, C_{pm} and C_{pmk}. Recently process capability indexes have been widely used in production industries for evaluating the process performance. Process capability indices are important topics since (Juran 1974) combined process parameters with product specifications to introduce the idea of process capability indices.

Firstly, the capability indices are used in the automotive industry. Ford Motor Company (1984) has applied C_p to track process performance and to reduce process variation. Since then, statistical process control (SPC) has been used in manufacturing and supplier selection processes (Pearn and Wu (2005). Greenwich and Schaffrath (1995) represented a simple transformation of the C_{pm}^* index, C_{pp}, which is called as a process incapability index. The C_{pp} contains an uncontaminated separation between information concerning the process accuracy and precision additionally to the information provided by the C_{pm}^* index. Pearn and Wu (2005) extended Cheng and Spiring (1989)'s research, which is developed by using one single sample, and introduced a Bayesian procedure to assess process capability index C_p based on multiple sample. In another study, Pearn and Wu (2005) examined the capability index C_{pk} and proposed

a Bayesian approach to test the general situation of the C_{pk} index with no restriction on the process mean. Hsieh and Tong (2006) developed a process capability index with combining the process capability index philosophy and quality loss function concept to evaluate the process capability for the qualitative response data. They used the process capability index formulas for Poisson and binomially distributed quality data sets. Chen et al. (2006) used C_{pu},C_{pl}, and C_{pn} process capability indices and multi-process capability analysis chart (MPCAC) to assess the integrated process capability for a multi-process product. They also introduced process capability index N_{pu}, N_{pl}, and N_{pn} for the data comply with a non-normal distribution. A non-normal multi-process capability analysis chart (NMPCAC) was used to evaluate process capability in a non-normal distributed data set. Linn et al. (2006) introduced capability index and price comparison (CPC) chart to evaluate candidate suppliers with considering quality and price simultaneously in the supplier selection process. The CPC chart integrates the process capability and price information of multiple suppliers and presents them in a single chart.Chen et al. (2008) considered process yield and expected loss. They stated that there is a directly proportional relationship between C_{pm} value and process yield, whereas C_{pm}value and the process expected loss are inversely related. In their study, the process capability analysis chart (PCAC/C_{pm}) is proposed to assess the integrated process capability for a multi-process product. Since the proposed chat uses the index C_{pm} instead of the C_{pk} index, it is able to measure effectively the effect of process centering on process capability. Morita et al. (2009) stated that the process capability index C_{pm} includes an economical concept since it is based on the Taguchi's quality loss concept and used the C_{pm} control chart to evaluate an operating cost. The operating cost considered in this study is composed of the sampling cost, the sample cost and the quality loss of failing to detect an out-of-control state. They aim to minimize the ceiling value of the operating cost based on the min-max criterion. Hsu and Yang (2010) proposed a process capability analysis chart (PCAC) to measure process capability for a multi-process produce based on C_{pk}. They developed a three phased PCAC method to improve Six Sigma technique. They conducted a case study on professional manufacturer of sewing machine and showed that the decision makers can able to apprehend whether the process of precision and accuracy with using the PCAC chart. Moreover, the decision makers can analyze the reasons of the inefficient process accuracy or precision on the PCAC model. Therefore, they stated that the PCAC model is also a preliminary analysis tool beside a measure tool. Pan and Lee (2009) developed a new process incapability index to accurately measure the process performance for both symmetric and asymmetric tolerances. The experimental tests show that the proposed process incapability index is a good tool when measuring of the manufacturing risk. Refaie and Bata (2010) presented a procedure for evaluating a measurement system and production process capabilities using Gage Repeatability and Reproducibility (GR&R). Three different applications are carried out in this study. According to the results, the procedure proposed shows a way to implementers in the evaluation of a measurement system and process capability analysis. Kuo (2010) proposed a C_p Capability chart running based on range. The chart gives information about a process performance and shows the ability of a process to meet requirements. Van der Merwe and Chikobvu (2010) advised a process performance index for average of samples from the new or unknown batches. They implemented the performance index in a medical tablet manufacturing company using Bayesian simulation method. Miao et al. (2011) aimed to assess process capability for multi-batch and low volume production, especially for the case that process mean and process variance are both unknown. Chakrabortty et al. (2012) aimed to justify the process capabilities where to process is capable or not and try to investigate the reason of incapability. The capability analysis is done in a soap manufacturing process for two different parameters. This study also represented the relationship between soap process parameters. Wooluru et al. (2014) conducted the capability analysis for a automotive industry. They applied the commonly used capability indexes by making critical assumptions. The aim of this paper is to give the general information about the capability concepts and methodologies. Chalisgaonkar and Kumar (2014) investigated issues of process capability and surface integrity for WEDM of pure titanium. Taguchi's approach was used to show the influence of machining parameters on the process capability index. Alverez et al. (2015) presented an empirical study to analyze the performance of the various estimators of capability index in the way of relative bias and relative root mean square error. Monte Carlo simulation was carried out to show the empirical performance of the capability index. Also, they compared the results in terms of the bias and efficiency. The aim of this paper is to present a capability analysis study for a medical bottle manufacturing process in pharmaceutical industry. This paper is organized as follows: process capability indices are presented in second section. Data used in the case study is analyzed statistically and case study is provided in third section. Section three also contains gage measurement system. Finally, conclusion is included in section four.

2. Process Capability Indices

The main idea of process capability indices is the combination of process parameters with product specifications. Determination of the product specifications based on the customer requirements is a critical issue in manufacturing. Juran firstly considered the process capability analysis in 1974. Ford motor company was the first organization to use capability indices. Since then, it has been a popular research area and studied by many researchers (Chen et al., 2006). In a manufacturing system, it is important to examine the process and evaluate the process performance to improve the production quality. Process capability analysis in which process capability indices (PCIs) are used to quantify the relationship between the actual process performance and the expected specification limits has been conducted to continuously improve process quality and productivity (Pearn and Wu, 2005). PCIs provide numerical information about the process quality and qualify the process capability. PCIs appraise the process capability in terms of relevance to process specifications and process variability, in this regard; the PCIs can be defined as statistical indicators of the process capability. PCIs also show the behavior of process or product characteristic to the specifications and provide quantitative measures of process performance (Senvar and Tozan, 2010). Generally, capability indexes assume that the quality data is distributed normally and the process is in control. Additionally, the process target and specification limits need to be determined based on customer needs in order to get effective results in capability analysis. In this study, the most common PCIs used in practice, C_p, C_{pk} (C_{pl}, C_{pu}), C_{pm} and C_{pmk} are considered and explained as follows.

C_p: This basic process capability index evaluates the performance of the process related to the predefined production specifications. In the literature, the C_p index is referred as the precision index. A C_p index value greater than 1.00 indicates that the process is capable and it is located between the specification limits. It produces information about the consistency of the process quality characteristics to the manufacturing tolerance. However, it does not take into account the location of the process with respect the specifications, since the measurement of the process average is not included in the index.Therefore, it is not able to evaluate the process centering. The formulation of the C_p index is given below. In the formulation, ULS indicates the upper-specification limit while LSL denotes the lower-specification limit. σ is the process standard deviation.

$$C_p = \frac{USL - LSL}{6\sigma} \quad (1)$$

C_{pk}: It is firstly introduced by Kane (1986). This capability index assumes that the process may not be centered between specification limits and takes into consideration the process location. However, this index is independent of the target and does not consider whether the process location diverges from the target. C_p equals to C_{pk} when the process is centered and both of them are classified in a yield based capability index.The index is presented by the following formulation.

$C_{pk} = Min[C_{pu}, C_{pl}]$ (2)

C_{pu} and C_{pl} indexes are generated from C_p index and they are related to the unilateral quality specifications. C_{pu} is used to evaluate smaller the better situation in a process and C_{pl} shows the quality capability for the larger the better type products. The formulation of index C_{pu} and C_{pl} are shown in below. It is understandable from their formulations that they only consider the one side of the quality specifications limit when evaluate the quality capability of a product.

$$C_{pu} = \frac{USL - \mu}{3\sigma'} \text{ , and } C_{pl} = \frac{\mu - LSL}{3\sigma'} \quad (3), (4)$$

C_{pm}: This capability index is based on the Taguchi loss function and it is also known as the Taguchi capability index. Chan et al. (1988) developed the process capability index C_{pm} which has an ability to reflect process loss.The advantage of this index is the process movements from the target are considered in the capability analysis additionally to the specification limits. Since C_{pm} based on the difference between process mean and the target value, it is able to produce more reliable information than C_{pk} about the location of the process mean.

$$\frac{C_p}{\sqrt{1 + \left(\frac{\mu - T}{\sigma}\right)^2}} \quad (5)$$

Where μ is the process average and T is the target value. The C_{pm} index is a loss-based capability index. If the process average on the target, C_{pm}, C_p and C_{pk} are equals to each other. With the changing meaning of quality, conformance to specification limits is become not enough for to produce quality products. According to Taguchi's quality philosophy, reduced variation from the target (T) value is necessary to have a capable process and satisfy customers. From this scope, Pearn and Lin (2004) showed in their study that the index C_{pm} is often preferred to C_{pk} index, since it provides better customer protection. The C_{pm} index gives warning when the process output is off target.

C_{pmk}: Pearn et al. (1992) first explored the C_{pmk} index which is the combination of C_{pk} and C_{pm} indices. The C_{pk} index is the most generally

$C_{pmk} = min\{C_{du}, C_{dl}\}$ where, (6)

$$C_{dl} = \frac{\mu - LSL}{3\sqrt{\sigma^2 + (\mu - T)^2}} \quad (7)$$

and,

$$C_{du} = \frac{USL - \mu}{3\sqrt{\sigma^2 + (\mu - T)^2}} \quad (8)$$

The index C_{pmk} is more sensitive to the movement between the process mean μ and the target value T than the other three indices C_p, C_{pk}, and C_{pm}. So, the C_{pmk} value reduces more rapidly than those basic index values when the process mean μ departs from the target value T (Pearn and Lin, 2002).

3. Data Evaluation and Case Study

In this study, an experimental case study is carried out in a medical bottle manufacturing company. The company produces medical packages such as pet and glass bottle. Critical quality characteristics of the products are determined based on the customer requirements. The predetermined quality characteristics of the medical bottle are weight, thickness, height and diameter. The production performance of the process is evaluated by monitoring the periodic observations related to critical quality characteristics.

The quality control is made three times in a day, and the defective items are classified as scrap and rework at the end of the each batch. Analyzed propriety in this case is external diameter of medical glass bottle. The diameter specification limits for the medical glass bottle are 48 ± 5 mm. In order to collect experimental data, every hour a random sample of five bottles is taken and the average bottle diameter of the sample calculated. Total subgroup size is determined as 20 in which each subgroup contains 5 items. The process mean is 47.83 mm and the standard deviation is 0.75 mm. Firstly, X-bar and R chart are drawn to monitor whether the process is in control condition or not. The results of the X-bar and R charts for the data are obtained from statistical software MINITAB 17 is given in Figure 1;

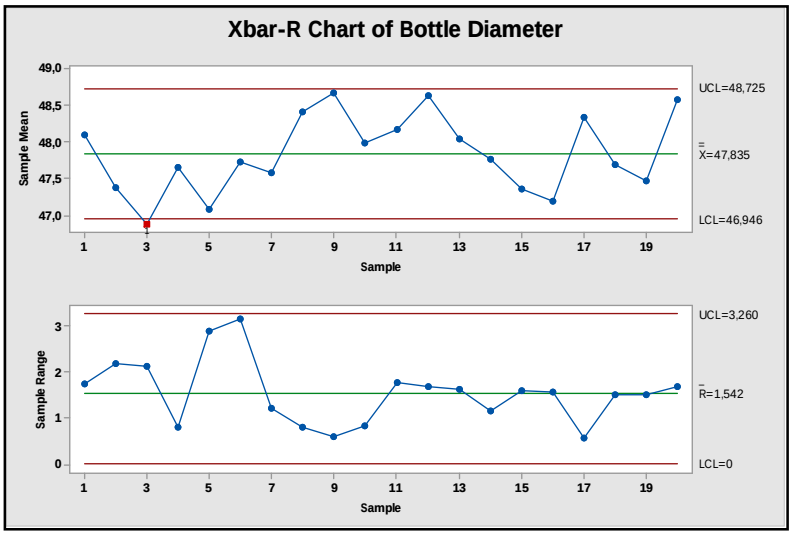

Figure 1: Control charts for preliminary data with trial control limits

As seen in Figure1, there is out of control point on the X-bar chart at subgroup three which means there is an assignable cause of variation is present. All plotted sample range is within the control limits. Therefore process is out of control condition. In this case, the process is stopped and investigation and corrective action is started for the process.

3.1. Establish the Revised Central Line and Control Limits

Since, subgroup three for the X-bar chart is an assignable cause, it is discarded from the data and new $\bar{\bar{X}}$ and $\bar{R}$ values are computed with the remaining data. The new central line and control limits are shown in the Figure 2;

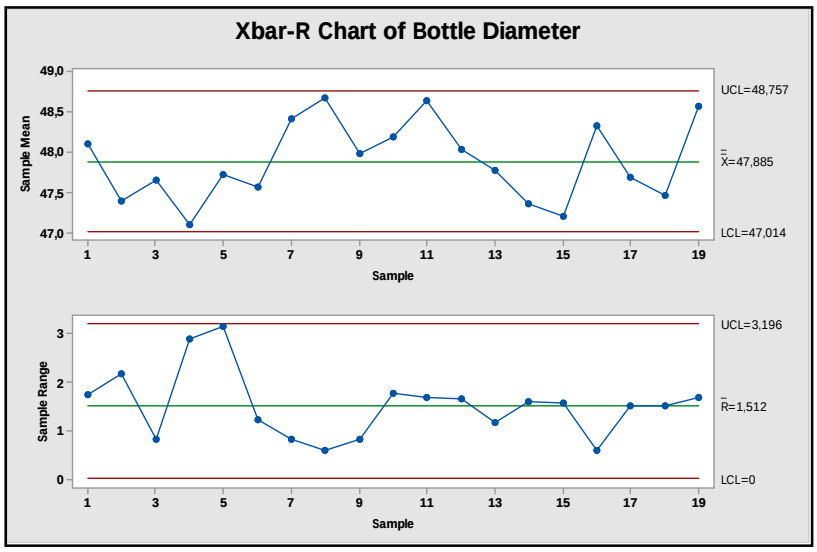

Figure 2: Control charts for data with revised control limits

All the points fall within the control limits, so the chart shows that the process is in control condition.

3.2. Process Capability Analysis Application

According to process capability analysis assumptions which are determined by Kotz and Montgomery (2000), after the process stability has been approved, normality testes are applied on the data. Histogram and probability plot are used to check the normality of the data.

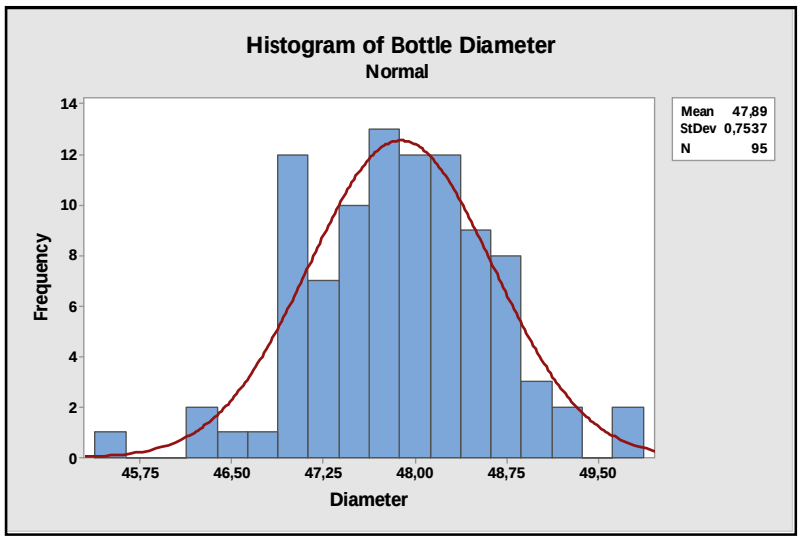

Figure 3: Histogram for the medical bottle data

The histogram of medical bottle diameter (Figure 3) seem to be approximately symmetric about to means which indicates that the data normally distributed.

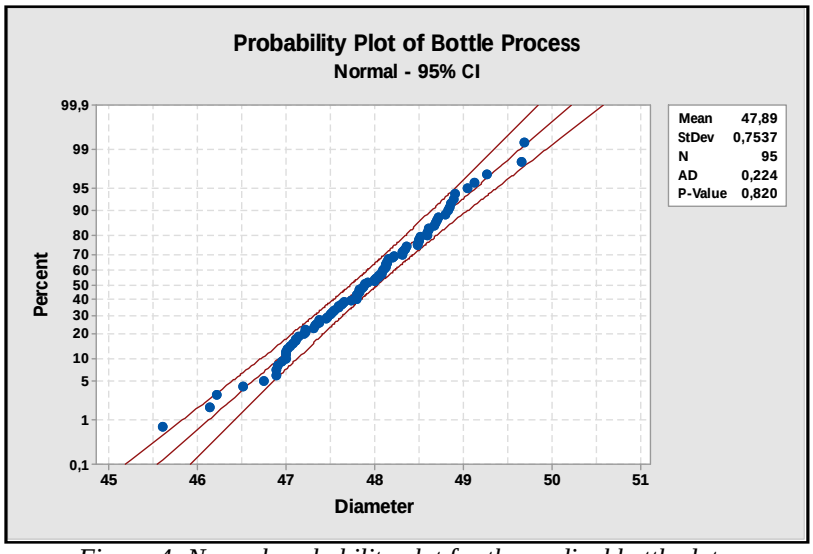

Figure 4: Normal probability plot for the medical bottle data

Figure 4 shows the test results for normal probability plot for the medical bottle data derived from MINITAB 17 statistical software. The results indicate that the process mean: 47.89, standard deviation: 0.75, Anderson-Darling test statistic value: 0.224 and p-value: 0.820. It is assumed that the data is distributed normally since p-value is greater than the significance level (α=0.05).

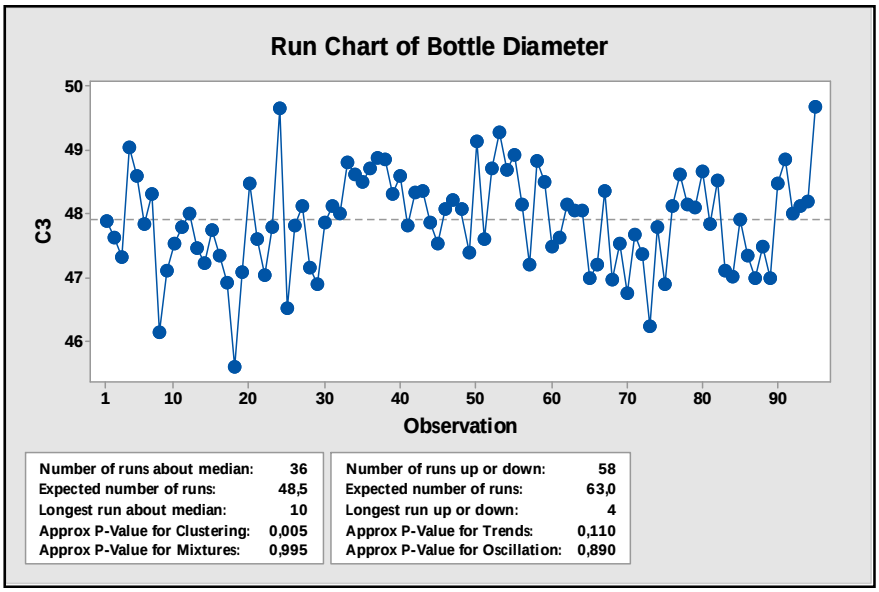

Figure 5: Run chart for the medical bottle data

As per the run chart, p-values for mixtures, trend and oscillation are greater than the significance level (α=0.05). According to this, samples obtained from the process can be called as random. However, p-value for clustering is lower than the significance level (0.05) which means special causes may affect our process. Thus, possible sources are investigated and measurement system analysis is applied to investigate gage capability.

3.2.1. Calculation of Gage and measurement System Capability

Process capability analysis is an effective method to evaluate the performance of process. However, measurement system may include variability based on the products themselves, the operator conducting the measurements and the equipment used to perform the measurement. Disregarding this variability when analyzing the process capability may cause unreliable judgment about the capability of the process. For this reason, gage capability study should be applied to get rid of inappropriate decisions.

The aim of using gage measurement system is to assess the accuracy of outputs for offer to customers, and to evaluate the statistical control and capability of the process. Decision makers need to use accurate and precise data while applying the statistical process control. Nevertheless, observations may contain measurements errors lead to variation in process additionally to the true value. Total variability in process is composed of product variability and gage variability. Therefore,

$$\sigma_{total}^2 = \sigma_{product}^2 + \sigma_{gage}^2 \quad (9)$$

$$\sigma_{product}^2 = \sigma_{total}^2 - \sigma_{gage}^2$$

$$\sigma_{product} = \sqrt{0.5680 - 0.4224}$$

Thus, the standard deviation of the bottle diameter is calculated as, $\sigma_{product} = 0.39$. Measuring equipments may not indicate a true value because of problems stems from accuracy and precision. Precision is the degree of variability individual observations or measurement results obtained from sample. The Precision/Tolerance (P/T) ratio is generally used to estimate of measurement system precision. Measurement system precision is the ratio between total measurement error and the part tolerance which shows the ability of measurement system to gauge the product quality characteristics. It is formulated as below (Pan, 2006):

$$\frac{P}{T} = \frac{5.15\sigma_{gage}}{USL - LSL} x100\% \quad (10)$$

Where σ_{gage} stands for standard error of variability of measurement process and tolerance shows width of specification.

Precision Tolerance Ratio	Acceptance Level
< %10	Accept
%10 - %30	Conditional Acceptance
> %30	Reject-Take corrective action

Table 1: Measurement System Requirements

P/T value shows ratio of the precision of the measuring system to the allowed tolerance. The precision of measuring equipments are computed by using P/T ratio (10) as follows:

$$\frac{P}{T} = \frac{5.15 * 0.65}{53 - 43} \cong 0.3$$

The P/T ratio of measuring equipments is determined as %30. According to Measurement System Requirements (Table 1), the value is evaluated as conditional acceptance. Large P/T ratio indicates that the process P_{pk} is lower than the true value and there is a risk to classify defect-free product as a defected or reject it. However, when the process capability value is higher than two, this situation can be underestimated (Stamatis, 2003). In this study, since P_{pk} value of the process is greater than 2, we can assume that the high variations in measurement system do not hinder the process. Thus, the current measurement system is suitable for using in the control process.

Afterwards the three assumptions are ensured; the process capability of the medical bottle production can be evaluated.

General process indices such as C_p, C_{pk}, and C_{pm} and C_{pmk} are calculated to evaluate the process capability of the medical bottle production.

The process capability report for medical bottle manufacturing process is derived from statistical software MINITAB 17 is given in Figure 6.

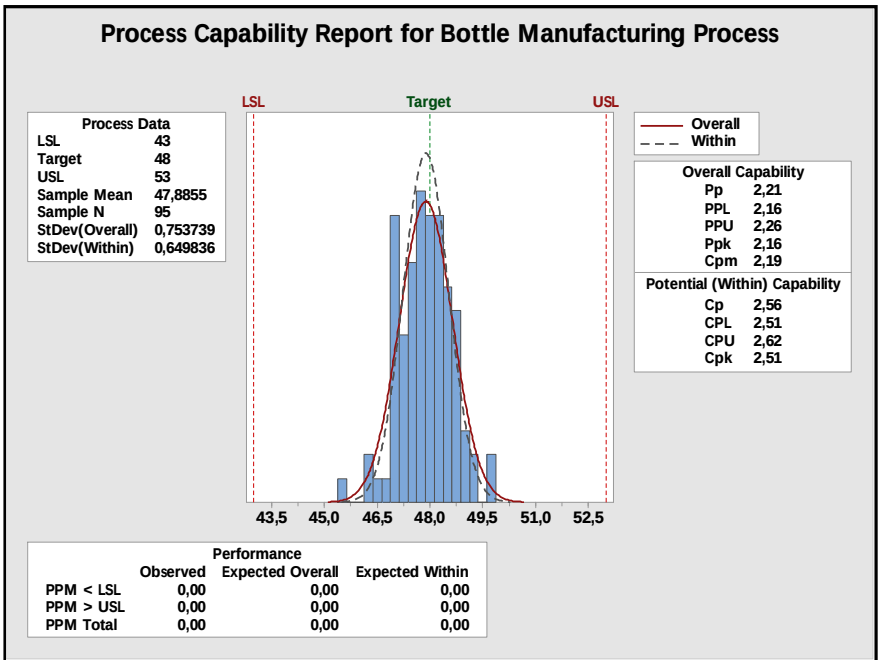

Figure 6: Process Capability Analysis of the Process

Table 2 shows the process capability index requirements.

Index Value	Quality Condition
$C_{pk} < 1.00$	Inadequate
$1.00 \leq C_{pk} < 1.33$	Capable
$1.33 \leq C_{pk} < 1.50$	Satisfactory
$1.50 \leq C_{pk} < 2.00$	Excellent

Table 2: Process Capability Index Requirements

The range-based estimate of standard deviation (σ') that states the variability within each subgroup is computed based on subgroup ranges. In the corresponding formulation (11), R stands for the average range and d_2 denotes the adjustment factor which is 2.326 for five sample size. On the other side, the sample standard deviation (σ) is based on the combination within subgroup and between subgroup variation.

$$\sigma' = \frac{\overline{R}}{d_2} = \frac{1.512}{2.326} = 0.65 \quad (11)$$

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x-\bar{x})^2}{n-1}} = 0.75 \quad (12)$$

P_{pk} capability index expresses the current process capability whether meets the product specifications or not. P_{pk} index only differs from C_{pk} index in terms of the estimate of the standard deviation used in the denominator as seen in (14), (15). P_{pk} and C_{pk} indices are similar to each other when the overall and within standard deviation values are closed. As seen in the Figure 6, overall standard deviation (σ) is 0.75 and within standard deviation (σ') is 0.64, as a result of this P_{pk} and C_{pk} are respectively 2.16 and 2.51.

$$C_p = \frac{USL - LSL}{6\sigma'} = \frac{53-43}{6*0.65} = 2.56 \quad (13)$$

$$C_{pk} = Min\left[\frac{USL-\mu}{3\acute{\sigma}}, \quad \frac{\mu - LSL}{3\acute{\sigma}}\right] = Min\left[\frac{53-47.89}{3*0.65}, \frac{47.89-43}{3*0.65}\right] = Min[2.62,2.51] = 2.51 \quad (14)$$

$$P_{pk} = Min\left[\frac{USL-\mu}{3\sigma}, \quad \frac{\mu - LSL}{3\sigma}\right] = Min\left[\frac{53-47.89}{3*0.75}, \frac{47.89-43}{3*0.75}\right] = Min[2.26,2.16] = 2.16 \quad (15)$$

$$C_{pm} = \frac{USL-LSL}{6\sqrt{\sigma^2 + (\mu - T)^2}} = \frac{10}{6\sqrt{0.5625 + 0.0121}} = 2.19 \quad (16)$$

$$C_{pmk} = \frac{C_{pk}}{\sqrt{1 + \left(\frac{\mu - T}{\sigma}\right)^2}} = \frac{2.51}{\sqrt{1 + 0.286}} = 2.47 \quad (17)$$

According to the results obtained from the calculations above, the medical bottle production process is capable due to the process mean is centered between specification limits (C_p =2.56). Additionally, the process is called 'super' since the C_{pk} value equals to 2.51 (as seen in Table 2).

4. Conclusion

In this study, performance of a medical bottle manufacturing process is appraised using different capability indices (C_p,C_{pk}, C_{pm} and C_{pmk}). Before the evaluation of the process, normality of the data is tested using some statistical tools like control charts, histogram and probability plot. Also, gage measurement is carried out for the observations. When an analyst uses the same equipment, different measurement values may occur. Since, measurement errors are inevitable in real life applications for most of the production processes, gage measurement errors have investigated whether the sample data are contaminated by measurement errors or not. If the firms neglect the effects of the measurement errors sourced by operators and equipments, this condition can bring about improper decisions and financial losses. The results indicate that the medical bottle production process is capable to produce the product meet customer requirements. According to the Motorola standards, performance of the production process is expressed as super capable. However, single characteristic observation may not sufficient to assess overall production process quality. For the future research, multivariate process capability indices can be used to handle corresponding drawback.

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