

The process capability to fulfill specifications with an application in pharmaceutical tablets weights

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ABSTRACT

This research aims to identify one of the methods of statistical quality control, which is represented in the indicators of the Capability Process and explains its importance and how to use it for knowing the extension of the process to fulfill the specifications through several indicators with a statement that through practical application on one of the pharmaceutical products (Paramol Tablets Weights) one of the products of Yemeni Drug Company for Industry and Commerce (YEDCO). Hence, the results showed that the permits of process specifications of the tablet weight are equal to about 5 standard deviations, which is less than the standard practices, which are 8 standard deviations. Therefore, the capacity of the process for tablet weight is $C_p < 1$, which is an undesirable state; because the production process is unable to satisfy the specifications. The CPK indicator shows that the process is decentralized and hence the inability of the process to fulfill the specifications; therefore, the company has to revise the limits of Paramol tablet weights specifications and to expand it as the company adopts numerous pharmacopeias in its operations. It must select the pharmacopeia that gives specifications which can make the process capability indicator and the index of process concentration in their standard state ($C_p, C_{pk} = 1.33\text{mg}$).

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1. Introduction

Industrial companies rely on the control of the quality of their products on the basis of scientific approaches represented by statistical methods of control such as admission inspection plans and quality control plans in all phases of production (inputs, outputs, and during the production process) for the purpose of providing high-quality products with minimal effort and low costs and work to improve them continuously. Therefore, statistical control is defined as “the organizational process for activities which measure the actual performance of quality and its conformity with standard specifications, and then take the necessary corrective measures for these activities wherever they exist.” Furthermore, the statistical control seeks to know the extent of conformity of the product to the previously prepared specifications by subjecting

it to checking and inspection in all its production stages so as to avoid deviations and faults before they occur, reduce them and explain their causes when they occur, and take corrective measures at appropriate times, through analysis of capability process and evaluating within specifications by several indicators called process capability indicators.

The fundamental problem that the research strives to study is determined by the fact that many industrial companies lack the use of statistical techniques in a scientific way to measure the process capability so as to fulfill specifications and improve the quality of production, which is represented by an indication of process capability of the production process through which production can be achieved with fewer faults.


The importance of this research comes as many of our new-born industries face strong competition by foreign products, due to augmenting of mistakes and defects that they suffer from, so, these companies must develop, improve and control the level of quality for their products.

This research aims to identify one of the methods of statistical quality control which is represented in the indicators of the production capability process; elaborating its importance and how to use it for

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knowing the extent of the process to meet the specifications, which mean obviously producing of cells whose dimensions fall within the specifications established or not, through several indicators, with an indication of this through practical application on one of the pharmaceutical products (Paramol tablet weights), one of the products of Yemeni Drug Company for Industry and Commerce (YEDCO).

2. Production process

It is an entire apparatus of resources including individuals, equipment, money, methods of work, etc. that correlate with converting the inputs into the outputs of International Organization for Standardization (ISO, 1994) and determining the capacity (resilience) of the process is considered as an essential and important part of the process for continuous quality improvement. Due to the assumption that most measurements of quality characteristics follow the normal distribution, the range between $(\bar{x} + 3\sigma_x)$, $(\bar{x} - 3\sigma_x)$ which includes 99.73% of the area under the normal distribution is taken as the capability or possibility of the process provided that the process is statistically stable, as the following relationship shows (Juran and Gryna, 1988).

$$\text{Process Capability} = UCL - LCL = 6\sigma \quad (1)$$

Hence, we can say that there is a difference between the control limits and the limits of the specifications; the control limits are calculated when using a machine or materials and the people involved in the production process, while on the other side, the limits of the specifications come from the design specifications, which are not related to machines or materials or any other part of the production process that produced the product. In the department of researches and development of companies, the importance of design for manufacturing had been increased as the designing for manufacture is considered obviously as the system that links the capability of the process that produces the product with the design of the total product and its specifications limitedly. Therefore, a case "outside of statistical control" does not mean outside of specifications while, in fact, there are a lot of processes under control creating totally different products away from specifications (Lynch and Werner, 1992).

3. Process capability

Due to the previous definition of process and from the previous relationship, the capability of the process can be defined as the extent leading to shattering of the outputs resulting from the stable interaction and homogeneity with the passage of

time for process elements that shift the inputs into outputs meanwhile the requirement for stable interaction and homogeneity of process elements during time means statistical stability of the process. The capability of the previous process is rewritten using sample statistics after checking the stability of the control panel \bar{x} and S as follows:

$$\text{Process Capability} = UCL - LCL = 6\hat{\sigma} \quad (2)$$

where $\hat{\sigma}$ estimating the standard deviation that is evaluated from the limitation of the control chart.

UCL the upper limit for the capability of the production process, and LCL the Lower limit for the capability of the production process.

$$\hat{\sigma} = \frac{UCL-LCL}{6} \quad (3)$$

Due to the specifications, they are related to the needed quality requirements to be achieved for the quality feature. They concentrate on measuring this feature in one X. Such specifications should include the permit limitations as represented with the two limits of specifications $LSL \leq x \leq USL$, which mean that the specifications contain tolerances whether on two sides or on one side.

Hence, the process capability relationship with specifications can be determined by limiting the extent of process capability to match or exceed its specifications, as shown in Fig. 1 (The range of process capability currently to fulfill the specifications). Determining through several indicators which we are going to recollect successively.

- Capability Index Cp: It refers to the level or ratio of the difference between the two specifications; the actual process given as the following:

$$C_p = \frac{USL-LSL}{6\hat{\sigma}} \quad (4)$$

where $\hat{\sigma}$, the standard deviation of the process output is estimated since the standard deviation of the process output in practice is unknown and is estimated by $\hat{\sigma}$ from the sample data, and is calculated as follows; $\hat{\sigma} = \frac{\bar{R}}{d_2}$ or $\hat{\sigma} = \frac{\bar{S}}{C_4}$ In the case of partial groups, but in the case of individual observations, it is calculated with $\hat{\sigma} = \frac{\overline{MR}}{d_2}$ The indicator Cp takes the following values;

The process is capable of specification fulfillment whenever $C_p > 1.0$.

The processing capacity is marginal or limited in relation to meeting specifications when $C_p \approx 1.0$.

The process is unable to meet the specifications when $C_p < 1.0$, meaning that some of the process outputs do not meet the specifications set for it.

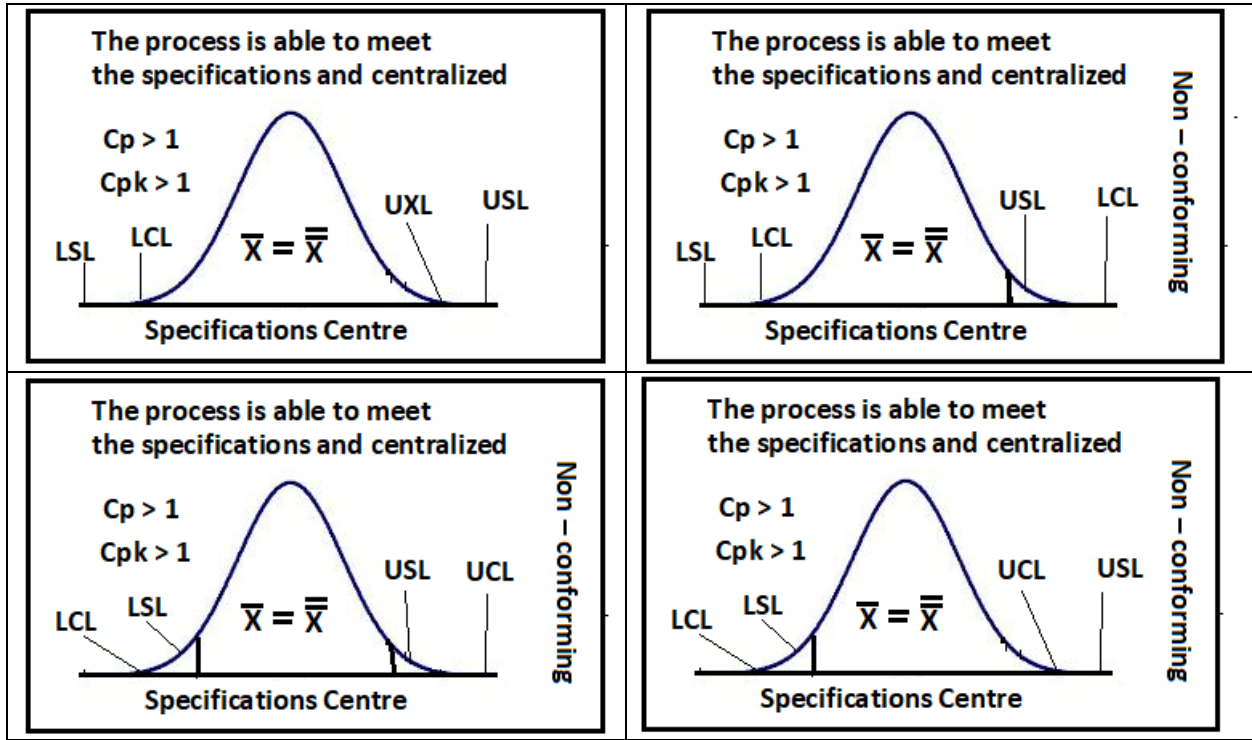


Fig. 1: Relationship of the operation ability with the specifications

From practical experience, it has been found out that the best economic indication is $C_p = \frac{8\sigma}{6\sigma} = 1.33$ indicating that specifications permits are within 8σ , which some industrial companies use.

In regard to capability indicator in case of the one-sided specifications; in this case, the estimated index is calculated as follows:

A case of higher specifications Limit:

$$C_{PU} = \frac{USL - \mu}{3\sigma} \tag{5}$$

A case of lower specifications Limit:

$$C_{PL} = \frac{\mu - LSL}{3\sigma} \tag{6}$$

where μ is the population mean and estimated from the sample data \bar{x} .

- Capability Ratio Indicator (Cr): It is the ratio of the actual dispersion of process outputs to the permissible range and is calculated by finding the inverse of the estimated indicator (Cp), which means as bellow':

$$C_r = \left[\frac{1}{C_p} \right] (100) = \left[\frac{6\sigma}{USL - LSL} \right] (100) \tag{7}$$

This indicator measures the ratio of the process used to the permissible range of specifications. The previous equation indicates that the relationship between the capability indicator and the estimated ability ratio is inverse. For example, Fig. 1 shows that the incapable operations ($C_p < 1$) have a greater

dispersion of their outputs than the permissible dispersion, and then we find that the percentile of their use of the permissible range of specifications is more than (100%), while this ratio is less than (100%) and in capable operations where the capability indicator (Cp) values exceed one true ($C_p > 1.0$). Table 1 shows some values of the estimated indicator (Cp), the nonconforming unit, and the used ratios of specifications.

Table 1: Some values of the estimated indicator (Cp), the nonconforming unit, and the used ratios of specifications

used ratios of specifications	nonconforming unit	USL-LSL	Cp
%200	133614.5	3 standard deviation	0.50
%100	2699.9	6 S.D	1.00
%75	66.1	8 S.D	1.33
%66.7	6.8	9 S.D	1.50
%60	0.6	10 S.D	1.67
%50	0.00198	12 S.D	2.00

- An indicator of production process concentration Cpk: Fig. 1 in mentioned earlier shows another indicator which is an indicator of production process concentration Cpk as obsessed with measuring of the concentration of production process while Cp doesn't care about such centralization (location of the arithmetic average of process outputs for the two-sided specifications) as limited to the determination of process fulfillment possibility with the specifications allowances. Moreover, in the same Fig. 1, we find that the process is capable of specifications fulfillment ($C_p > 1.0$), but this process is obviously decentralized. Consequently, the product appears higher unmatched or non-conformist (USL) and hence it is necessary to calculate an indicator of process centralization to determine the extent of

process concentration influence to fulfill the specifications same as the following relationship (Mears, 1995),

$$Cpk = \text{Min} (CPL, CPU) \tag{8}$$

So,

$$C_{PL} = \frac{\bar{\bar{x}} - LSL}{3\sigma}, C_{PU} = \frac{USL - \bar{\bar{x}}}{3\sigma}$$

represents an indicator of process concentration to fulfill both the upper and lower limits of specifications, respectively. But in case of occurrence of two sides for specifications (higher and lower), the values of Cpl and Cpu have to be calculated, and the lower value one should be taken as riskier due to the fulfillment of two-sided specifications, and hence this indicator has to be taken in three cases as follows:

$$Cpk > 1.0 - Cpk \approx 1.0 - Cpk < 1.0$$

Therefore, we find that $Cpk \leq Cp$, that is, Cpk cannot exceed Cp, so the economic criterion of Cpk is 1.33, as well. In similar dimension, the previous Fig. 1 the value of Cpk according to four cases in comparison to Cp value (Farnum, 1994) whereas the relationship between Cp and Cpk as this formulation $CPK = (1-K) CP$ noticing the down following (Montgomery, 2007): $CP \geq CPK$ permanently; $CP = CPK$ when the process is centralized; $CP > CPK$ when the operation is decentralized; $0 = CPK$ when the mean of the process output is equal to one of the upper or lower specifications limits; If it is < -1 (CPK), this means that all process outputs locate outside the limits of the specifications; $0.5 (CPU + CPL) = CP$; CP measures Potential Capability while CPK measures Actual Capability.

Table 2 shows the recommended lower values for the estimated indicator values according to the process description.

Table 2: The recommended minimum values for the estimated indicator values

(One-Sided Specifications)	(Two-Sided Specifications)	Process description
1.25	1.33	Existing operations
1.45	1.50	New operations
1.45	1.50	Existing safety operations, Durability, or critical milestones
1.60	1.67	Existing safety operations, Durability, or critical milestones

To measure the distance of the center of the process (μ) from the target value (half the distance between the two-sided specifications), we should use $K = \frac{|(USL+LSL)/2 - \mu|}{(USL - LSL)/2}$, and the value of K becomes between zero and one ($0 \leq K \leq 1$).

- Capability Index C PM: Although the indicator Cpk is used to measure the capability of the decentralized operations, this indicator lonely is considered an incomplete scale to measure the

centering of the process, and therefore to measure the center of the process, a better capability indicator must be used, and it takes the following formula,

$$C_{PM} = \frac{USL - LSL}{6\sqrt{\sigma^2 + (\mu - T)^2}} = \frac{USL - LSL}{6\sqrt{\frac{\sum_{i=1}^N (x_i - T)^2}{N}}} \tag{9}$$

where μ is the mean population of summation, estimated at $\bar{\bar{x}}$ the standard deviation of the population, estimated at T, is the target value, which is half the distance between the limits of the two-sided specifications (USL+LSL), and N refers to the viewing number. Also, it is patently noted that the CPK and CPM values are equated with the CP indicator value when the arithmetic mean of the process is equal to the target value ($T = \mu$). The relationship between the indicators CPK, CPM, and CP in the case of the target value T are equal to the half distance between the limits of the two-sided specifications 0.5 (USL+LSL).

$$C_{PK} = C_p - \frac{1}{3} \sqrt{\left(\frac{C_p}{C_{PM}}\right)^2 - 1} \\ \Rightarrow C_{PM} = \frac{C_p}{\sqrt{1 + 9(C_p - C_{PK})^2}} \\ \Rightarrow C_p = C_{PM} \sqrt{1 + 9(C_p - C_{PK})^2} \tag{10}$$

- Capability Indicator CPMK: The CPMK is regarded as a third-generation indicator, which is close to the CP indicator, and is given by the following formula;

$$C_{PMK} = \frac{\text{Min}[USL - \mu, \mu - LSL]}{3\sqrt{\sigma^2 + (\mu - T)^2}} \tag{11}$$

We find that if the process is centered in the target value $T (= \mu)$, the values of the two indicators CPMK and CPK are equal, while the value of CPMK is less than CPK in the case that the arithmetic means of the process differs from the target value ($CPMK < CPK$) for each $T \neq \mu$. When ($M = T = \mu$) then: $CPMK = CP = CPK = CPM$ and the following equation describes the relationship between the four estimated indicators.

$$CPMK = (CPM \cdot CPK) / CP \tag{12}$$

4. Previous studies

Zuhair (2012) studied the effect of design tolerances upon process capability. The research aims to study the external diameter of the gasket piston because of an increasing diameter of gasket from the specification which results in an increase in applied pressure on hup cylinder which results difficult in moving of piston while decreasing the diameter from specification does not seal off the preventive process flow of liquid causes of entering air and easy of piston motion. Effects appear the solution for modifying the variability of the process

from (0.03) to (0.02) is the best solution because that solution will reduce the percentage of defective production from 15.8% to 6.7 and the percentage of rework will reduce to zero without that is effecting upon the mean of the process.

Ata (2012) improved the quality of welding wire by using the process capability index case study applied in Al-hilal industry. The research use process capability index, which is the most important statistical techniques to improve the quality where they can manufacture the product with low percentage defect, and it will be applied in welding wire which produced in Al-hilal industrial .and because of the importance of extrusion process which carried out on the extrusion machine, and a large number of errors during this phase, will be + determined the process capability index for this machine through the application of the methods of process capability. The results of the research as the following: 1-The process was controlled statically. 2- There has been an improvement in the process capability index. 3-Dispersion of data is considered acceptable. 4-Eliminate the average normal dimension specified by the designer by (0.01mm). 5- Low the percentage of defect outside the upper limit, which became (3%).

The statistical tools can be used to control product quality, which turns on the essential definition presentation on the quality, its system of control, the diagnostic and the precise main statistical tool analysis used in the control of quality that is considered like main requirements to guarantee the success of the quality controls and their mastery as well as the reduction of the costs the no quality. Therefore, it leads toward the improvement of the quality, the increase of the production, of the elevated profit and know if the Algerian industrial enterprise uses these tools inside the factories and what is the method used on the control of quality adopted. It has been noted through this survey that the method used for the control of the quality to the society doesn't give any efficient results, because the use of the statistical tool discovers several mistakes that arrive in some stages of the production operation, what drove to the release of the products non-compliant to the level of the shop choice.

Statistical quality control and process capability analysis for variability reduction of the tomato paste filling process (Rábago-Remy et al., 2014).

The purpose of this investigation was to reduce the variability of the canned tomato paste filling process coming from a tomato processing food industry that has problems with the net weight of their processed product. The results of the process capability analysis showed that 35.52% of the observations were out of the specifications during the months in the study, which generates a real capability of the process (Cpk) of 0.124, and it indicates that the process does not have enough ability to fulfill the required specifications by the firm. In addition, it was noted that the process had only 77.49 parts per million (ppm) out of

specification. This situation places the tomato paste filling process as a world-class quality process.

5. Hypotheses of research

Practicing capability indicators of the production process keenly helps at the ability of the process to fulfill the specifications.

6. Practical application

For the purpose of knowing the extent of the process's capability to fulfill the constitutional specifications of Paramol tablets, it is necessary to study this ability (Capability), as we mentioned on the theoretical side that the relationship of the process's capability to specifications must be determined by the extent of the process's capability to match or exceed its specific specifications (The extent of the process's capability in its current state to fulfill specifications), and is determined by an indicator called the Capability Index, which is the ratio of the difference between the specifications and the ability of the process, and in our process here (the weight of the Paramol tablets), the limits of the specifications were the minimum limit of specifications: LSL=527.7mg-Central Line of Specifications: CLC=Target=555.5mg-Maximum Specifications: USL=583.3mg.

Since the stability of the weight of the Paramol tablets is achieved, it is possible to calculate the process capability of the weight of the tablets as follows:

$$\hat{\sigma}_x \text{ Process Capability} = UCL - LCL = 583.2 - 515.3 = 67.9$$

$$\Rightarrow \hat{\sigma}_x = 67.9 / 6 = 11.3$$

Therefore, the indicator of the process's capability to weigh the tablet is 0.82.

As we mentioned in the theoretical field, the practical experience has set the best economic standard for the value of (Cp) to (1.33), which means that the specifications allowances (USL-LSL)=8 σ . It is clear in our case here that the permits of operating specifications are 55.6mg, while the estimate of standard deviation is 11.3mg, which means that the permits for operating specifications of the tablet weight are equal to about 5 standard deviations. This is less than the standard practice and is 8 standard deviations. Therefore, the process's capacity for tablet weight is Cp<1, which is an undesirable state; because the production process explicitly cannot fulfill the specifications.

Whereas Cp is concerned only with determining whether the process can fulfill specifications; There is another indicator that is the index of the centralization of the production process, Cpk, as it is concerned with measuring the centralization of the production process, and we compute this indicator according to the relationship (40-4), and as long as we have a limit of specifications (higher and lower)

then the values of Cpl and Cpu are calculated and taken as the lowest of the two values, so they are equal to Cpk; because the lower value is the riskiest in terms of fulfilling the specifications, and therefore we find the following:

$$C_{pl} = \frac{\bar{\bar{x}} - LSL}{3\hat{\sigma}} = \frac{549.2 - 527.7}{33.9} = 0.63$$

$$C_{pu} = \frac{USL - \bar{\bar{x}}}{3\hat{\sigma}} = \frac{583.3 - 549.2}{33.9} = 1.006$$

$$\Rightarrow C_{pk} = 0.63$$

Therefore, we find that $C_{pk} < C_p$, which means that C_{pk} cannot exceed C_p , and therefore the economic criterion is the value of C_{pk} is 1.33 as well, as is the case in C_p , and the following Fig. 2 shows the analysis of the process's capability, and therefore the process is unable to meet the specifications in addition for being decentralized. This confirms the inability of the process to fulfill the specifications, and therefore the company has to rethink the limits of specifications of Paramol tablet weights and expand them. Since the company adopts many pharmacopeias in its operations, then it must select the constitution that gives specifications for the

process that makes an indicator Process Capability and process centering index in their standard state ($C_p, C_{pk}=1.33\text{mg}$).

Furthermore, the company must reconsider the periodic maintenance of the machines, as we clearly saw during the work that the Paramol tablet press machine has stopped for many times due to its production of defective tablets (changing of tablet color) was observed with just a look. Such conduct was due to repeated failures in the machine due to lack of maintenance periodicity, and this was confirmed by the results of the questionnaire in addition to the machine's antiquity, so it is also necessary to replace this machine with a more modern machine. Moreover, the company must approve specific sources of raw materials having international fame and conclude contracts with them to take into account the conditions of both producer and consumer, and hence it is, unfortunately, wrong for the company to import its raw materials from several sources in search of the lowest price, and not to conclude contracts that include the requirements of examination and inspection, and only depend on absolute confidence and complacency in case of facing defective discovery in its purchased items. Fig. 2 shows an analysis of the capability process.

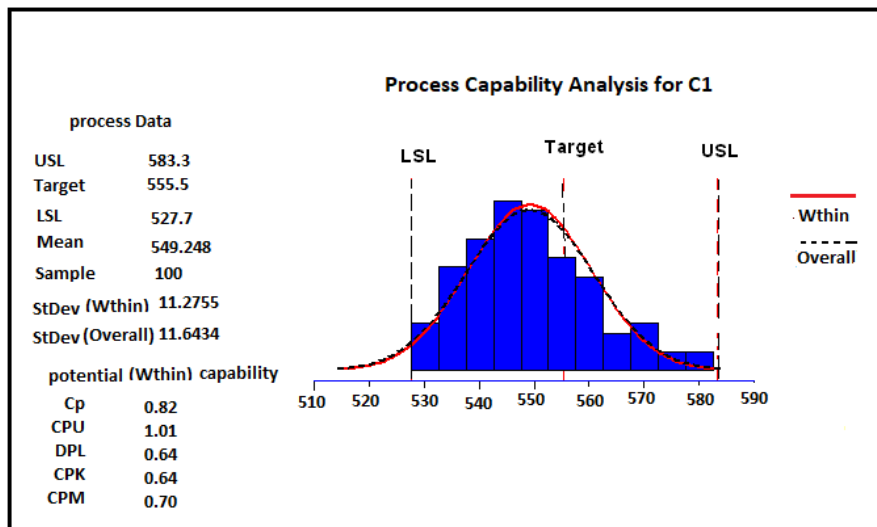


Fig. 2: An analysis of capability process

7. Results

The practical work results show that: The allowances of operating specifications for tablet weight are equal to about 5 standard deviations, and that is less than the standard practices, which are 8 standard deviations. Therefore, the capacity of the process for tablet weight is $C_p < 1$, which is an undesirable state; because the production process is unable to fulfill the specifications.

8. Recommendations

The company should reconsider and expand the specifications of Paramol tablet weights. As the

company adopts several pharmacopeias in its operations, it must choose the constitution that gives process specifications that make the process capability indicator and the process centering index in their standard state ($C_p, C_{pk}=1.33\text{mg}$). Also,

1. The company must reconsider the periodic maintenance of the machines, as we clearly saw during the work that the Paramol tablet press machine had stopped for many times due to its production of defective tablets (changing of tablet color) that was observed with just looking, and this was due to repeated malfunctions of the machine due to Lack of periodic maintenance.
2. Replacing old machines with modern ones.

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Compliance with ethical standards

Conflict of interest

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