

**Research Article**

# EVALUATION OF TABLET COMPRESSION MACHINE CAPABILITY BY STATISTICAL PROCESS CONTROL METHOD – A CASE STUDY

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**Abstract**

This case study discusses the use of statistical process control (SPC) for evaluating tablet compression machine capability and efficiency in pharmaceutical industry. The tablet compression process is found to be out of control in compression machine A since the process capability indices for hardness parameter is  $C_p = 1.2$  and  $C_{pk} = 0.9$ . In this case the process is not centered and has chance for producing tablet out of specification limit. The compression machine B and C is capable of producing the tablets with the hardness within pre-determined specification limit. In this case the tablet hardness is spread within the specification range and the process is centered and found to be in control with process capability indices more than 1. The study found that though the hardness of the tablet compressed in the compression machine A, B and C are within specification limit, the tablet from compression machine A has chance to fall outside the specification limit and suggest to

closely monitor during the compression in Machine A for this product.

**Keywords:** Statistical Process Control, Tablet Compression Machine, Process Capability, Control Chart.

**INTRODUCTION****Statistical Process Control – An Overview:**

Statistical process control is a powerful problem solving technique used for monitoring, controlling, analysing, managing and improving a process using statistical methods. The philosophy of statistical process control concept is the output of a process can be brought into a state of statistical control by means of management and engineering intervention.

It is used in quality assurance program in total quality management (TQM). Total quality management is a philosophy to bring continuous improvement activities in an organisation during product manufacturing stage.

**Advantages of Statistical Process Control:**

SPC could improve process performance by reducing product variability and improving production efficiency. SPC gives quality product thus by reducing variability and defects and ultimately improving business competitiveness. The success and failure in SPC does not depend on company size or resources, but relies on appropriate actions taken to solve the problem. The advantages include (a) Maintaining desired degree of conformance to product specification (b) increases product quality and provide evidence of quality. (c) monitors the variation of a process and minimize the deviation from target value and plays a major role in process improvement.

**Control chart and Process Capability:**

The objective of control chart are to monitor variation due to assignable causes and take corrective actions. Control chart is a process monitoring and control tool. The variation in process can be monitored by using a control chart by plotting a sequence of measured quality data along with process control limit. In general this variability arises from three sources improper machine adjustment, Op-

erator error or defective input materials. The information gathered from control chart can be used to calculate process capability. Process capability can be employed to predict machine performance. Having done that the machine performance will then be used to determine whether the process has a low or high variability. It can be used during the process to detect incoming quality problems and eliminate the products that are out of specification limit. There are two types of capability indices Cp and Cpk.

Process capability compares the output of an in-control process to the specification limits by using capability indices. Process capability index uses both the process variability and the process specifications to determine whether the process is "capable". We are required to compare the output of a process with the process specifications and make a statement about how well the process meets specification. A capable process is one where almost all the measurements fall inside the specification limits. Most capability indices estimates are valid only if the sample size used is 'large enough'. Large enough is generally thought to be about 60 independent data values.

Variability occurs in every production process. Quality can be measured by using process capability index. Cp measures the spread of specification relative to three sigma process and Cpk measures how well a given process is generating a specific characteristic with respect to specification limit. Thus it reveals process spread and location with respect to the nearest design specification.

Cp, Cpk Formula

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

$$C_{pU} = \frac{(USL - \bar{X})}{3\hat{\sigma}}$$

$$C_{pL} = \frac{(\bar{X} - LSL)}{3\hat{\sigma}}$$

$$C_{pk} = \text{Min}(C_{pU}, C_{pL})$$

#### STUDY METHOD:

Case study method was adopted since it involves an in-depth investigation and appropriate when trying to answer the "how" and "why" questions

of research. The aim of this case study was to use SPC technique to evaluate tablet compression machine capability and efficiency. Three compression machine in the production facility of a pharmaceutical company was involved in this study and designated as machine A, machine B and machine C. For this study the X-bar chart was selected for performing data analysis. The chart will provide information about the process variation. The case study was analysed manually by hand written formula. In tablet compression machine A, B and C, the quality characteristic selected for the study is tablet hardness parameter. Samples were collected from tablet compression machine during compression process. 10 Tablets were collected for each sample and tested for hardness and recorded and then calculated for mean value. Following same procedure for 9 more samples mean values were calculated. The specification limit for hardness parameter was 1 to 6 kg/cm<sup>2</sup>.

#### RESULT AND DISCUSSION:

The result of the case study conducted are summarised as follow:

Tablet hardness is a important quality parameter to fulfil the product specification requirement and also it has impact of bioavailability parameter of few drugs. Especially they have huge impact on BCS class II drug due to their low solubility nature. Apart from this other in process test parameter were performed as routine test during compression of the tablets. Figure 1 shows the X-Bar chart from the tablet hardness of the tablet compressed in compression machine A.

X-bar chart shows all the samples lie within the given upper control limit (UCL) and lower control limit (LCL). From the x-bar it is obvious that consecutive points were hovering from above to below the mean values. This shows the existence of some form of trends that require in-depth investigation. The process capability values Cp and Cpk for tablet compression machine were 1.2 and 0.9 respectively. It can be concluded that tablet produced by compression machine are still within upper and lower control limit. However, if left unchecked it may result in tablet hardness that fall out of specification limit. It can be concluded that machine is capable of producing consistent hardness since it has Cp value larger than 1 (Cp > 1). In this case the

Cpk value of tablet compression machine is 0.93 ( $Cpk < 1$ ) which mean the process is not centered. Since the process is not centered, it need to be closely monitored to see the up and down swing of the mean values are still within the specification limit. The same batch blend was compressed in machine B at higher speed of the compression ma-

chine. The hardness of 10 reading calculated during the compression process shown in X-bar chart figure 2.

Figure 1 – X-Bar chart of hardness in compression machine A.

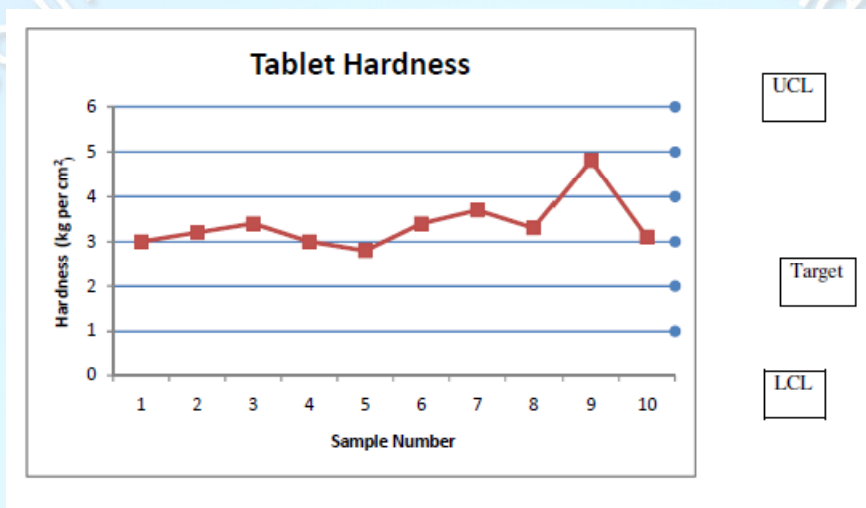
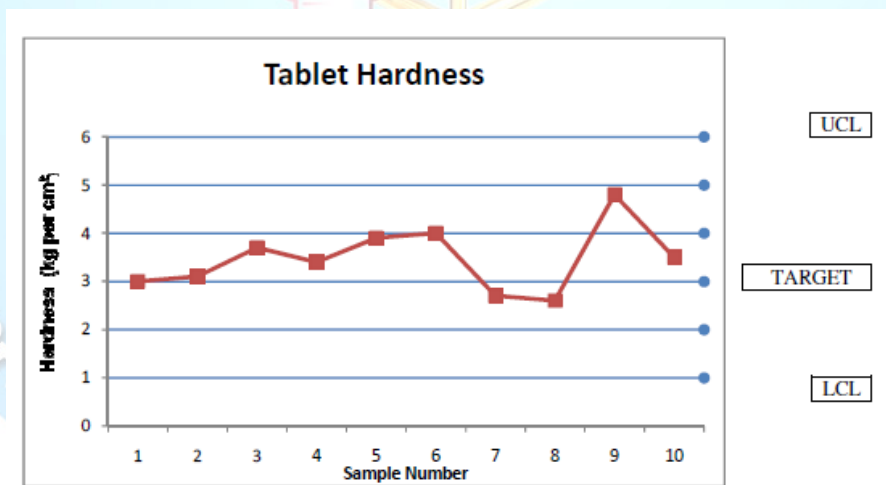


Figure2 – X-Bar chart of hardness in compression machine B.



The Cp and Cpk value was about 1.2 and 1.5 respectively. It can be concluded that machine is capable of producing tablet within the specification limit and the process is centered. The same batch blend was compressed in machine B at higher speed of the compression machine. The hardness

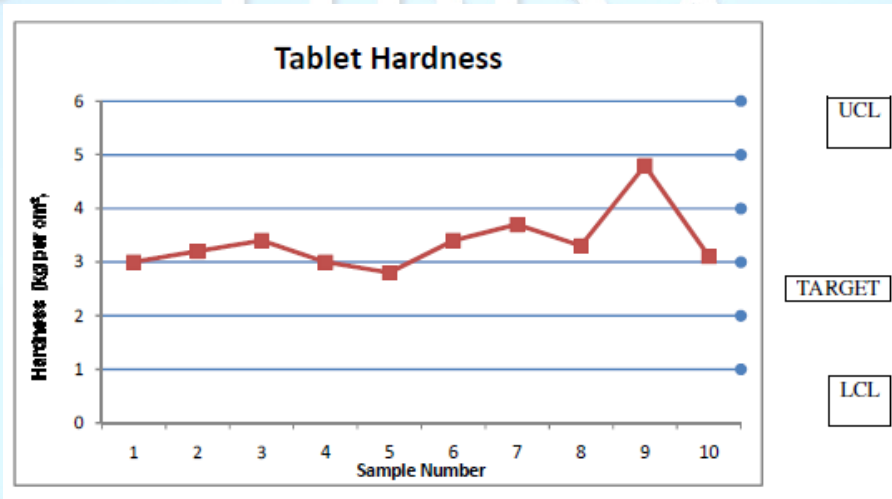
of 10 readings calculated during the compression process shown in X-bar chart figure 3. The Cp and Cpk value was about 2.2 and 2.9 respectively. It can be concluded that machine is capable of producing tablet within the specification limit and the process is centered.

**CONCLUSION:**

The case study conducted in the 3 compression machine had showed the importance of SPC for monitoring and ensuring the tablet compressed meet the pre-established specification limit. Statistical process controls were used to evaluate machine capability and process centerness of the compression process during compression stage of the product. In machine A though the hardness of the tablet were within specification range, the study conducted suggest to find out root cause

since Cpk was less than 1 and take necessary action. In compression machine B and C, the tablet hardness was within statistic control limit. Cp and Cpk values were above 1 suggesting the consistent and centerness of the compression process. The observed difference in machine A might be due to machine factors such as design, machine specification, machine speed, machine condition, die and punches used ,hopper design etc.

**Figure 3 – X-Bar chart of hardness in compression machine C**



A part from machine factors, granule characters like segregation during unloading of granules from blender and storage in in- process container and segregation in hopper during compression process have to be considered for investigation study.

In general these variations might also be seen as batch to batch variation due to the effect of critical process parameters such as granulation time, granulation speed, binder concentration, binder addition rate, drying conditions, particle size distribution, blending time, segregation during storage of granules etc. Once the process capability index indicates a capable process, a routine process capable indices technique should be employed so that processes remain within the specification range. The process capability indices should be periodically calculated to assure process mean and spread has not changed adversely.

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