Carnauba Dispenser to Improve Coated Tablets Elegance

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Abstract *— This study describes the implementation of Six Sigma for improvement of the addition process of carnauba wax on coated tablets in a pharmaceutical industry. Due to the frequent complaints received from costumers for covered engraving on tablets with carnauba wax, the company carried out a Six Sigma project. The Six Sigma methodology provides an organized structure for problem analysis and problem solving. Using DMAIC phases the problem was defined; the variables influencing the process were measured; the causes for the tablet elegance defect were analyzed; improvements were scheduled and made until level of customer satisfaction were reached. A new tool was implemented for the addition of carnauba wax during coating drying step. The project implementation achieved to increase productivity and allowed process standardization, improving customer service and quality.*

Key Terms *— carnauba wax, coated tablets, coating, customer.*

PROBLEM STATEMENT

Customer satisfaction is one of the many factors that can contribute to the success or failure of a business. Customer satisfaction can be defined as the attitudes or expectations that customers form based on their experience with an organization. In fact, customer satisfaction is considered a quality measure. A customer experience, from their own perspective, can help understand how to best improve or change the products and services. This research work will be focused on a frequent complaint from patients taking coated tablets: covered engraving. As a pharmaceutical industry, the expectation is to develop a method to improve carnauba application so it does not affect the elegance of the tablet.

Research Description

Some patients claim to find tablets whose engraving is covered by something described as a light-colored dust. This is commonly associated with the use of carnauba on the final stage of the tablet coating process. “Carnauba wax is widely used in food, due to its physicochemical characteristics with a predominance of esters and inert and stable components [1].” Currently, an operator adds the amount of carnauba established per standard operating procedure (SOP) manually from a bag directly to the coated pan in the drying step. This procedure may cause extra carnauba to adhere onto some tablets, covering the tablet logo. The development of this research consists in a design proposal of a tool with the appearance of a saltshaker. This tool, called carnauba dispenser, will be introduced to distribute the product more evenly to the tablets. This work will help to meet customer’s requirements and answer their needs while delivering the best quality of our products.

Research Objectives

The main objective of this work is to decrease by 20% the customers complaints related to coated tablet appearance and positively impact on the operating costs of the company. To achieve this, a new tool needs to be created for the carnauba addition step during tablet coating process, and subsequently implementation and control of the proposed improvement plan. This way, the results of improvement in the process towards reduction or elimination of the identified waste can be validated. This allows to understand how the task is executed and to standardize an operating method for all those involved in its execution.

Research Contributions

It is important to monitor the quality of delivery of a product or service in order to make customers more loyal. This approach keeps the providers with their eyes open to identify the changes that occur in the industry and to have the information in time to adapt and grow. The applied procedure provides a tool to reduce or eliminate a common defect and improve coated tablets appearance (see Figure 1). Therefore, customers will be fully satisfied, creating a link with the brand.

Figure 1
Model of Customer Satisfaction [2]

LITERATURE REVIEW

Tablet coating consists of applying an edible paint on the surface of a pharmaceutical dosage form to achieve specific benefits. When a coating solution is applied to a batch of tablets in a coating pan, the surfaces of the tablets get covered with a polymeric film. Then, tablets are dried by passing hot air through the surface of the tumbling pans. The film eventually forms a non-sticky dry surface. "This technique involves parameters such as the spray pattern, drop size, and nozzle spacing (in addition to multiple other non-spray related parameters) which must all be precisely controlled in order to ensure uniform distribution of the coating material. [3]"

The coating may be formed either by a single application or may be developed in layers through the use of multiple spraying cycles. Rotating coating pans are often used in the pharmaceutical industry. "Coating is an additional process in tableting which causes an increase in production cost but it has many purposes: To mask the disagreeable odor, color or taste of the tablet, to offer a physical and/or chemical protection to the drug and to control and sustain the release of the drug from the dosage form. Also, it can be used to incorporate another drug which create incompatibility problems, to protect an acid-labile drug from the gastric environment and to increase the mechanical strength of the dosage form. [3]"

It is most desirable that tablets are easy to swallow. The addition of carnauba wax helps patients swallow the tablets. A very small amount of the excipient is added onto a batch of tablets after they have been sprayed and dried. The wax and tablets are then mixed together in the rotating pan for a few minutes before unloading from the tablet coating machine. However, coating should be uniform and should not crack under stress to ensure the quality of the final product.

All pills have a code on them, which is also called engraving. The engraving is a series of numbers and/or letters that allow to identify the pills and under no circumstances should it be covered by any material. Most coating defects are due to some parameter failure: temperature, drum speed, humidity, etc. "Tablet defects impart financial burden on pharmaceutical companies. From a clinical perspective, defected tablets may result in therapeutic failure as well as reducing patient compliance. Due to the magnitude of this issue, attempts have been made to understand the mechanism that contributes to tablet defects arising during commercial manufacture and transport. [4]"

The problem to be evaluated in this study is tablets with carnauba excess resulting in covered engraving. It has been identified that the root cause of this defect is human error. Currently, we do not have any tool to evenly add the carnauba to the tablets. For this reason, when the operator manually adds the material, it can cover the surface of some tablets instead of being distributed in the rest of the batch. Lean Manufacturing defines as a *muda* a wasteful process or activity that adds no value. The *muda* of defects has costs which increase proportionally to how long it takes for the defect to be detected. A defect that makes it through to your

final product leads to poor customer satisfaction eventually affecting the reputation of the company.

METHODOLOGY

Introduction

To ensure a better distribution of carnauba in the tablets, a tool similar to a saltshaker was implemented. The new carnauba dispenser consists of a stainless steel container with small holes that is manipulated by holding the Teflon handle (see Figure 2). Its campaign length and cleaning frequency will be the same as the rest of the coating equipment as per SOP. The quantity of carnauba previously weighed and shipped in a bag will be transferred to the carnauba dispenser.

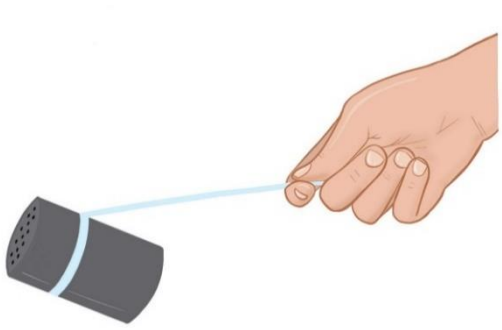

Figure 2
Carnauba Dispenser Prototype

When adding the carnauba in the corresponding step, the dispenser will be introduced through the acrylic window of the coater. Then, performing multiple agitations, the carnauba will be randomly distributed trying to cover most of the batch. Finally, the window is closed by the operator and batch record instructions are followed. Once the cool down is finished, an elegance test is performed on 1250 random tablets from the coated pan to detect minor, major and critical defects. Batches are shipped to main warehouses, were they are inspected and packaged to sell them to the market. Defective are reprocessed and these generate an additional cost.

Objectives

Once the carnauba dispenser is implemented and batches go to market, the plan is to ask customers to complete a post-purchase survey. The questions will be easy to respond and should be narrowly focused with enough context for the respondent to answer accurately. It is important to avoid questions that are not directly relevant to the survey's purpose. The goal is to keep the number of closed-ended survey questions limited to 7 or below. This quantitative survey will provide numerical data to analyze and evaluate corrective action. Following up on a customer's complaint gives the opportunity to find out if the solution is effective, if problem was solved or if the customer has questions or difficulties. This helps with the constant improvement of products and services. Cost and resources management ensure that the job is completed at or below the approved budget with the most effective use of resources.

Analysis Techniques

Six Sigma is a scientific and statistical quality assessment for all processes in the organization through measurement of quality level. It is a project-driven structure that employs an organized methodology, called DMAIC. It consists of five phases: Define, Measure, Analyze, Improve and Control. Six Sigma methods are commonly used to achieve customer satisfaction. "This is a well-structured methodology that can help a company achieve expected goal through a continuous improvement methodology. [5]" Six Sigma objectives were integrated to reduce a specific defect on coated tablets for customer complaint resolution. This approach helps to improve a process which eventually can enhance profitability and customer satisfaction through statistical techniques. To validate the designed survey, five quality assurance associate responses will be used after inspecting lots where the carnauba dispenser was implemented to conduct hypothesis test.

RESULTS AND DISCUSSION

The process started with a Define Phase. The problem faced by the organization was that the operational method of adding carnauba wax was covering tablets engraving (see Figure 3). This was resulting in reportable defects and extra efforts for support and resolution of customer complaints.

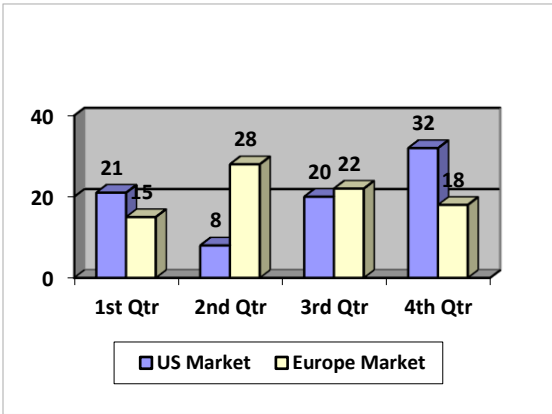

Figure 3
Customer Complaints in 2019

The customer complaint analysis process is defined by using process mapping (SIPOC) as shown in Table 1. Through this Six-Sigma tool, the data collection system and the resources required to carry out the improvement activity can be identified. Also, Critical to Quality (CTQ) specification table was prepared by measuring and monitoring process quality and level of control (see Table 2).

Table 1
Process Mapping (SIPOC) of Customer Complaint Analysis

Supplier (S)	Input (I)	Process (P)	Output (O)	Customer (C)
Customer	Complaint – Call, letter, mail	Resolution of complaints	Closed complaints	Patients
Customer Care	Discussion with customer, Action plan		Customer feedback	
Raw Material Supplier	Repair, Carnauba wax			
Quality Assurance	Compilation & Follow up meeting			

Table 2
CTQ Specification Table

NEED	CTQ	OPERATIONAL DEFINITION OF MEASURE	DEFECT DEFINITION	KANO STATUS
Reduce customer complaints by 20%	Coated tablets elegance defect	Satisfactory batches = Batches produced – Complaints	>10 complaints per market	Must be

The Measure Phase consisted of data collection to validate designed survey. Having clear the description of the problem to be taken up and having completed the Define Phase, we proceed to the collection of information to know the current state of the process to make the comparison with the information we obtain after the improvement. The results of the surveys are processed based on a scale where each question is assigned a numerical value so it can be analyzed to show the incidence of each of the variables. The Survey Design can be seen in Figure 4. The standard mean will be 3.2, which is the results of (1+1+4+5+5)/5. Therefore, the proposed null hypothesis is H_0: $\mu = 3.2$ and alternative hypothesis H_A: $\mu \neq 3.2$ where $\alpha = 0.05$.

Customer Survey Example						
Quality is our priority and we want to hear about you. Mark in front of each question the value that you consider represents your experience with our product.						
	Question	**5- Strongly agree** □	**4- Agree** □	**3- Neither agree or disagree** □	**2- Disagree** □	**1- Strongly disagree** □
1	Have you notice any tablet defect recently?	□	□	□	□	□
2	Have you found the logo of a tablet covered by light particles?	□	□	□	□	□
3	Have you ever reported a complaint?	□	□	□	□	□
4	If previously reported, your complaint has been resolved?	□	□	□	□	□
5	Would you recommend our products to anyone?	□	□	□	□	□
6	If you have any other corncern please add here: _____ □ N/A					

Figure 4

Survey Design

The next step is Analysis Phase. In this phase the intention is to analyze the data to identify the root causes of the problem and find the most appropriate improvement to implement. Lean Six Sigma methodology tools are used not only to reduce the production waste, but also to standardize the required methods for continuous improvement of the process so that it continues to operate efficiently and effectively. A brainstorming session was conducted by involving a cross functional team, which exposed causes for covered engraving related to carnauba wax. Brainstorming is known to identify the causes that affect a problem in a process. It is a recommended tool since it integrates the opinion of all the people who are part of said process. In this case, brainstorming was carried out with the opinion of the operators, the production manager and process owner towards the main problem, which was how to avoid excess carnauba in tablets. Among the responses obtained were: Bad distribution of the excipient by the operator, lack of operator knowledge, under pressure work, carelessness of the operator and lack of appropriate tool. As a result of these ideas, it was decided to make an Ishikawa diagram to find the possible root causes of the problem of defective tablets that are generated during the coating process (see Figure 5). The Ishikawa diagram is a tool that contributes to the identification of the root causes of a defined problem; for this reason it is decided to implement this diagram to solve the problem of the company. By analyzing each of the possible causes and implementing the Cause - Effect diagram by Kaoru Ishikawa, one must find the root cause or causes that originate the problem.

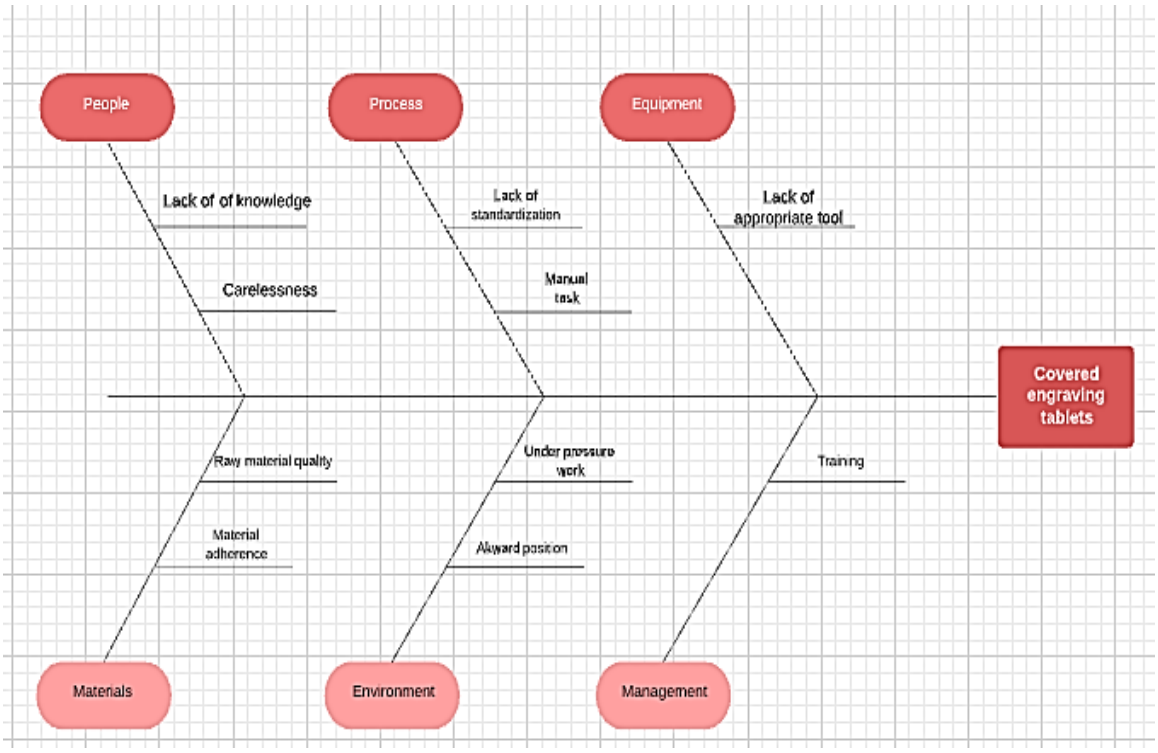

Figure 5
Ishikawa Diagram

Statistically, survey data was organized and subjected to T-test using Minitab to find if there is any difference between what the associates answered after the improvement and the standard responses. The hypothesis test shows a p value > 0.05 so null hypothesis is acepted (see Figure 6). This means that there is no difference between what they answered and the standard, so the survey can be validated and supplied to a sample greater than 30.

One-Sample T: Quality

Test of μ = 3.2 vs ≠ 3.2

Variable	N	Mean	StDev	SE Mean	95% CI	T	P
Quality	5	3.200	2.049	0.917	(0.655, 5.745)	0.00	1.000

Figure 6
Minitab T-test

At the Improve and Control Phase, the necessary corrective action needed for the validated process was identified. The use of carnauba dispenser was added to standard operating procedures for coating process. Also, process guides were discussed in the production area to emphasize its importance in order to mitigate human error due to lack of information on the manufacturing process. The implemented tool helped towards overall method improvement for taking action for the particular complaint significantly reducing more than 20% customer complaints for the specific coated tablet defect (see Figure 7).

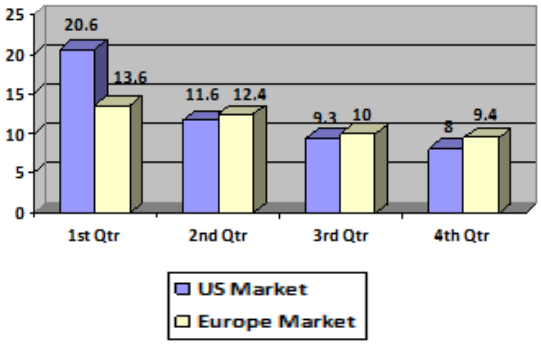

Figure 7
Customer Complaints in 2020

CONCLUSIONS

This new tool has considerably benefitted the organization by reducing customer complaints. The process also confirmed customer satisfaction surveys are valuable to hear the voice of the customer and rate performance. Appropriate feedback analysis can help to discover more improvement opportunities. Project management is in essence a problem-solving methodology that ensures timely and efficient delivery of the product or service intending to keep the customer satisfied, which in turn develops your business. Through all the daily actions, no matter how small, every company can be more competitive in customer satisfaction. This brings consistency and results while minimizing customer complaints.

The DMAIC approach of Six Sigma included training, measurement and data analysis tools to identify and eliminate the root causes, achieving better results. The qualitative and quantitative tools helped to identify, prioritize and validate the addition of carnauba method. Six Sigma's scheme guides to an effective problem definition and analysis during critical decision making. It is driven by close knowledge of customer needs, data, statistical analysis, and disciplined use of facts. This study demonstrates an approach to conduct real improvements and how Six-Sigma is embraced to improve the customer complaint resolution process of an organization, improve customer-supplier relation, and finally increase customer satisfaction.

The methodology in this research can be described as interactive problem-solving process. It is important for companies to have a standard way of addressing problems and solving them. Also, it is important to emphasize the responsibility at every level to identify problems and suggest ideas, creating positive attitudes towards the improvement process. A lean mindset promotes teamwork and a continuous improvement culture on any company. However, this transformation can be only achieved with leadership, support for improvement projects, and appropriate methods and tools. To successfully establish and maintain a culture of continuous improvement in all operations, the commitment and support of management is essential, providing the necessary resources to maintain motivation.

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