

DEFECTS IDENTIFICATION AND ANALYSIS OF A PHARMACEUTICAL PRODUCT USING PARETO AND CAUSE-EFFECT ANALYSIS

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ABSTRACT

Pareto and cause-effect analysis are two major tools to address quality issues. This paper focuses on the process of identifying and analyzing the defects of a pharmaceutical product using these tools. Pareto analysis is used to find out the major problems of the defective products and cause-effect analysis is considered to find out the main causes and sub causes behind that problems. To eliminate the causes and sub causes which are responsible to make defective products, it is very important to identify causes, sub causes and their exact location in the system. In this paper the main problems, causes, sub causes and exact location of causes and sub causes are identified using pareto and cause-effect analysis. Capping, edge-chipping and broken tablets have been found as the vital problems for producing defective products. Few root causes are identified though cause-effect analysis which are responsible for the mentioned problems.

Keywords: Defect Identification, Quality Improvement, Pareto Analysis, Cause-Effect Analysis.

1. INTRODUCTION

Pareto chart is a simple statistical chart, also known as Pareto diagram. It is useful for quality control. In the early nineteenth century, the famous Italian Economist Vilfredo Pareto developed this. Now a days, it is widely used in quality management to identify the vital few and trivial many. It looks like a cumulative bar chart. The lengths of the bars represent frequency or cost and arranged with the longest bars on the left and the shortest bar to right. The longest bar represents the vital few.

Pareto analysis is a statistical technique in decision making that is used for selection of a limited number of tasks that produce significant overall effect. It uses the Pareto principle - the idea that a large majority of problems (80%) are produced by a few key causes (20%). Pareto analysis is a formal technique useful where many possible courses of action are competing for your attention. In essence, the problem-solver estimates the benefit delivered by each action, then selects a number of the most effective actions that deliver a total benefit reasonably close to the maximal possible one. This is graphical tool for ranking problems from most significant to least significant. It depicts a series of vertical bars lined up in a descending order- from high to low- to reflect frequency, impertinent, or priority.

There must be many potential reasons, or "causes" which ultimately lead to create an adverse "effect". Here, the 'effect' is the quality problem. Cause Effect (CE) analysis is a tool for analyzing and illustrating a process by showing the main causes and sub-causes leading to an effect (symptom). It is sometimes referred to as the "Ishikawa Diagram", because Kauro Ishikawa developed

it, and the "Fishbone Diagram", because the complete diagram resembles a fish skeleton. The fishbone diagram is easy to construct and invites interactive participation. A cause-effect analysis generates and sorts hypotheses about possible causes of problems within a process by asking participants to list all of the possible causes and effects for the identified problem. This analysis tool organizes a large amount of information by showing links between events and their potential or actual causes and provides a means of generating ideas about why the problem is occurring and possible effects of that cause. Cause-effect analyses allow problem solvers to broaden their thinking and look at the overall picture of a problem. Cause-and-effect diagrams can reflect either causes that block the way to the desired state or helpful factors needed to reach the desired state. It is a graphic presentation, with major branches reflecting categories of causes, a cause-and-effect analysis stimulates and broadens thinking about potential or real causes and facilitates further examination of individual causes. Because everyone's ideas can find a place on the diagram, a cause-and-effect analysis helps to generate consensus about causes. It can help to focus attention on the process where a problem is occurring and to allow for constructive use of facts revealed by reported events. However, it is important to remember that a cause-and-effect diagram is a structured way of expressing hypotheses about the causes of a problem or about why something is not happening as desired. It cannot replace empirical testing of these hypotheses: it does not tell which the root cause, but rather what the possible causes are.

Major two types of cause effect diagram include and Process Analysis. Cause Enumeration is the most commonly used CE diagrams in industries. This indicates one by one all possible caused from brainstorming sessions and then classifies into groups. Specialists from concerned departments like engineering and design, procurement, quality assurance, maintenance, production etc. from the group. Participants in brainstorming session are encouraged to think freely and suggest from experience, judgment, anticipation etc. This method has the advantage that the list of possible causes will be more comprehensive because the process has a more free-form nature. The disadvantage is that it is more difficult to draw the diagram from this list rather than from scratch. This method of drawing a CE Diagram can be used in conjunction with brainstorming by using it to distil the brainstorm output down into a logical and useable set of information. A simple cause enumeration may not identify exact location of occurrence in complete process. A process analysis type CE diagram can do that. Its structure is totally different form the earlier type of CE analysis. It follows the process step by step and causes are listed as per process step. This, prior to developing a CE diagram, process flow chart is a must. Additionally, participation of the process owners is also must in the brainstorming session. The main advantage of creating this type CE diagram is its ability in pinpointing the exact location of occurrence. Both types of CE diagram can be used to determining cause. Both types of CE diagram can be used to determining causes. Finding out a cause and pinpointing its location may require both CE diagrams at a time.

Sanders [1] discussed the relevance of the rule of 80/20 and developed from the Pareto principle. Karuppusami and Gandhinathan [2] used Pareto analysis to identify and propose a list of few vital critical success factors (CSFs) of total quality management (TQM) for the benefit of researchers and industries. Jiang and Gainer [3] reported cases of robot accidents involving fatality, injury and non-injury were gathered from several sources (U.S., West Germany, Sweden and Japan) using cause- effect analysis. A method for cause- effect analysis of chemical processing systems has been developed on the concept of a signed directed graph by Umeda et. al. [4]. Sambasivan and Soon [5] used cause-effect analysis to identify the delay factors and their impact (effect) on project completion Malaysian construction industry. Gill [6] used Effect-cause-effect (ECE) methodology of theory of constraints (TOC) to examine the assumptions behind successfully managing business projects. Emery [7] developed a cause-effect-cause model to identify prerequisites for sustaining effective cross-functional integration as well as their temporal inter-relationships. The performance of milling and boring operation on ‘Gear Housing’ in CNC Milling Machine (DC-45), in terms of positional error and accuracy of the job, and a wide variation of the job in terms of quality improvement have been investigated by Dipak et. al. [8] using Pareto and cause-effect analysis. In this paper, Pareto analysis is used to identify the main problems and Cause- effect analysis is used to find out the causes behind the main problem. Pareto analysis is

used to find out the vital problem occurring in processing & compression, coating and blistering of products. Cause effect diagram is developed for the vital problem occurring in processing & compression, coating and blistering. Process type cause effect diagram is also developed to find out exact location of the problem. Data are taken after completing the production in processing & compression, coating and blistering.

2. METHODOLOGY

The processing & compression, coating and blistering sections have been taken for analyzing the defects of the product. During processing ingredients are mixed homogeneously and during compression the shape of the product is formed using compression machine. After completing the compression, products are sent to coating section to give a thin coating layer on products. In blistering products are filled into packets. In these sections, lots of defective products are produced. Data has been taken from these sections to identify and analyze the quality of the product. For Pareto analysis, samples of products are taken in consecutive ten batches and numbers of defective products from each batch are identified and defectives products are separated according to the types of problems. Then major problems are identified considering the percentage of defective. The causes and sub causes behind the main problem have been analyzed using cause-effect analysis.

3. PARETO AND CAUSE EFFECT ANALYSIS IN PROCESSING & COMPRESSION

Processing and compression are important steps to produce the pharmaceutical products. But lots of defective products are produced here. So, these two steps are taken for analyzing. Data are taken after completing the processing and compression of the product.

3.1 Pareto analysis

Data have been taken for the product after completing the Processing and Compression. Samples of products are taken in consecutive ten batches and numbers of defective products from each batch are identified and defectives products are separated according to the types of problems. The data for the product after processing and compression are shown in Table 1.

Table 1: Data for Pareto analysis (processing and compression)

Problems	Frequency	Percent defect (%)	Cumulative percent defect (%)
Capping	173	51.64	51.64
Weight variation	51	15.22	66.87
Mottling	46	13.73	80.6
Chipping	22	6.57	87.16
Friability problem	18	5.37	92.54
Thickness variation	12	3.58	96.12
Lamination	6	1.79	97.91
Others	5	1.49	99.41
Sticking	2	.59	100

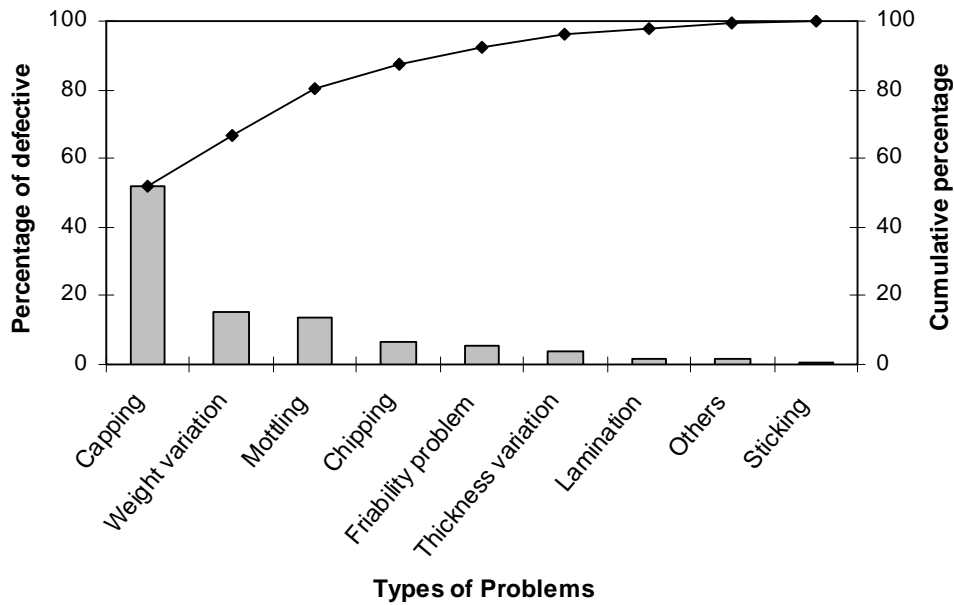


Fig 1. Pareto chart for processing and compression

After identifying the different types of problems and corresponding number of defectives a Pareto chart is drawn to identify the main problems which is shown in Fig. 1. From the Pareto diagram, the major problems are identified which are Capping, Weight variation and Mottling. These problems are responsible for 80.6 % of total defectives. Among these problems, capping is responsible for 51.64% of total defectives which is highest among all the problems. So, cause- effect analysis is performed only for “Capping”.

3.2 Cause- Effect analysis

This technique is used for identifying the causes associated with this particular problem. The causes have been identified through brainstorming and then establishing different cause categories like man, machine, method, measurement, material and environment.

Then all the causes have been allocated and placed under the appropriate major cause category. The root causes have been identified and these root causes should be amenable to action. After identifying the main problem, a cause- effect (CE) diagram is developed to find out causes and sub causes for the “Capping”. The cause-effect diagram is shown in Fig. 2. The main causes behind the capping are machine speed, wear and tear of die and punch, mixing, over drying and percentage of powder which are shown in Fig. 2.

4. PARETO AND CAUSE EFFECT ANALYSIS IN COATING

Coating, after processing and compression, is also an important step to produce the pharmaceutical products. But lots of defective products are produced here. Data are taken after completing coating of products.

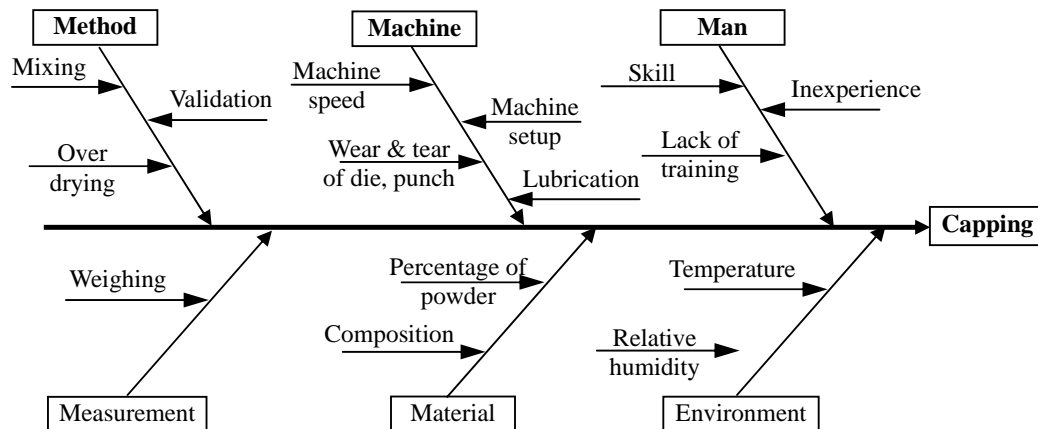


Fig 2. Cause-Effect Diagram of “capping” problem in processing and compression

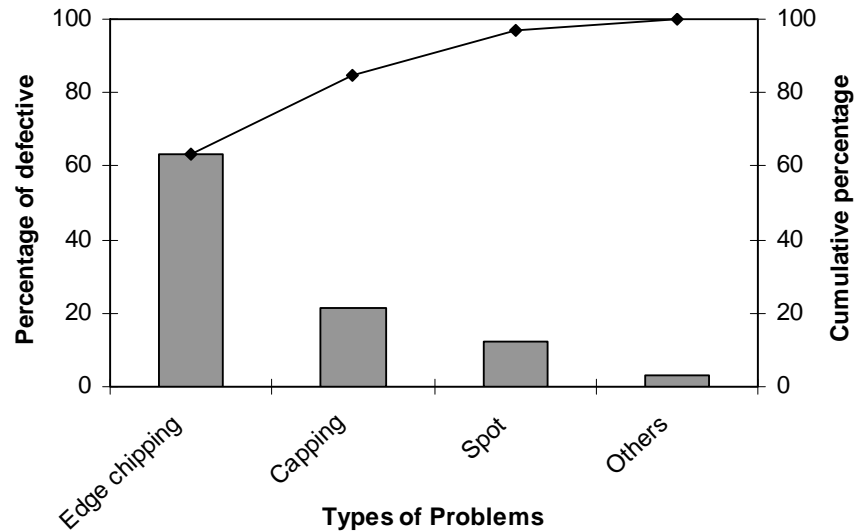


Fig 3. Pareto chart for coating

4.1 Pareto analysis

Data have been collected for the product after completing the coating. Samples of products are taken in consecutive ten batches and numbers of defective products from each batch are identified and defectives products are separated according to the types of problems. The data for the product after coating are shown in Table 2.

Table 2: Data for Pareto analysis (coating)

Problems	Frequency	Percent defect (%)	Cumulative percent defect (%)
Edge chipping	165	63.22	63.22
Capping	56	21.46	84.67
Spot	32	12.26	96.93
Others	8	3.07	100

After identifying the different types of problems and corresponding number of defectives a Pareto chart is developed to identify the main problems for coating which is shown in Fig. 3.

From the Pareto diagram, the main problem in coating is identified due to “Edge chipping”. This problem is responsible for 63.22 % of total defectives. So, cause-effect analysis is performed only for “Edge chipping”.

4.2 Cause- Effect analysis

After identifying the main problem, a cause-effect (CE) diagram is developed to find out causes and sub causes for “edge chipping” problem. The cause- effect diagram is shown in Fig. 4. The main causes behind the “edge chipping” are low solid content in solution, improper drying, low spray rate, high pan speed, low mechanical strength of coating and coating material which are shown in Fig. 4.

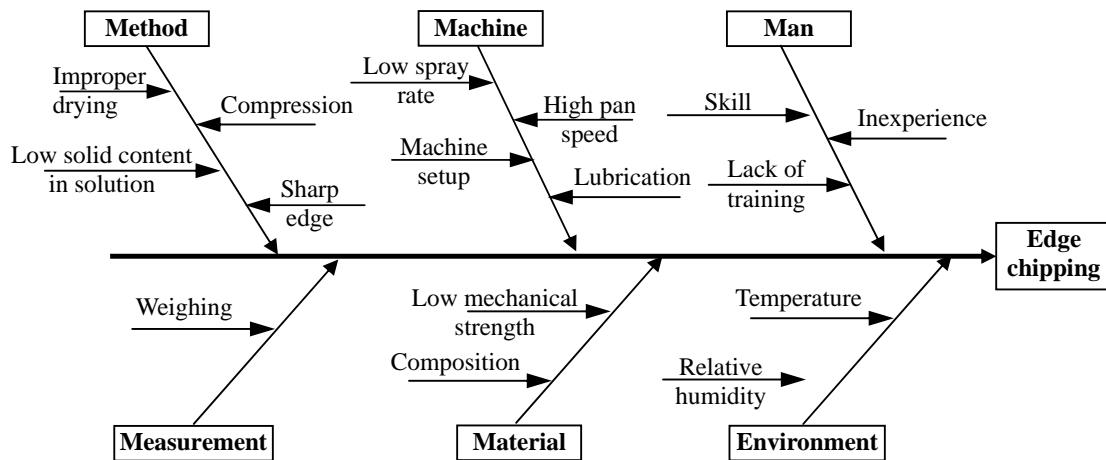


Fig 4. Cause-effect diagram of “edge chipping” problem in coating

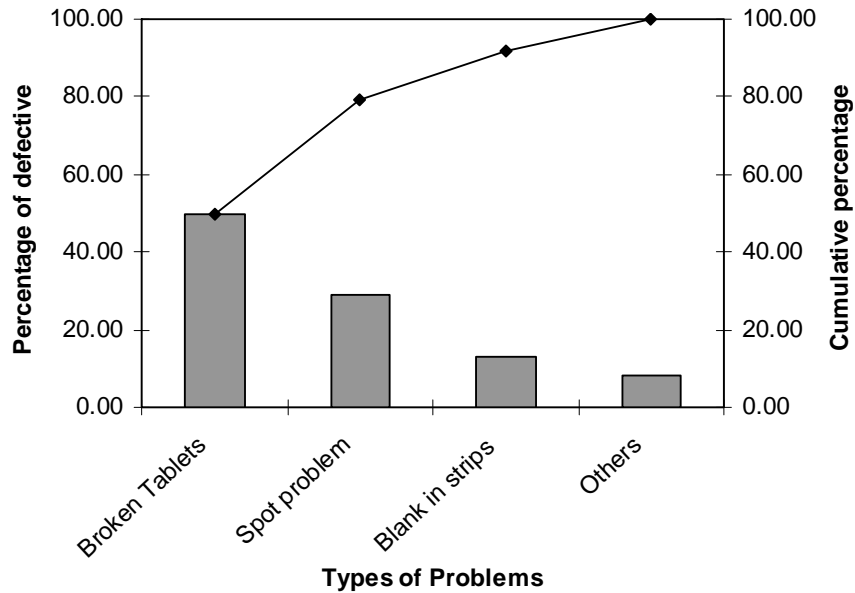


Fig 5. Pareto chart for blistering

5. PARETO AND CAUSE EFFECT ANALYSIS IN BLISTERING

Blistering, after coating, is the last step to produce the pharmaceutical products. But lot of defective products is produced here. Data are taken after completing blistering of the product.

5.1 Pareto analysis

Data has been collected for the product after completing the blistering of products. Samples of products are taken in consecutive ten batches and numbers of defective products from each batch are identified and defectives products are separated according to the types of problems. The data for the product after blistering are shown in Table 3.

From the Pareto diagram (Fig 5), the main problem is identified due to "Broken Tablets". This problem is responsible for 50% of total defectives. So, cause- effect analysis is performed only for "Broken Tablets".

Table 3: Data for Pareto analysis (blistering)

Problems	Frequency	Percent defect (%)	Cumulative percent defect (%)
Broken Tablets	74	50.00	50.00
Spot problem	43	29.05	79.05
Blank in strips	19	12.84	91.89
Others	12	8.11	100

5.2 Cause- Effect analysis

After identifying the main problem, a cause- effect (CE) diagram is developed to find out causes and sub causes for "Broken Tablets" problem. The main causes behind the "Broken Tablets" are processing, compression, sorting, skill and vibration during auto filling which are shown in Fig. 6.

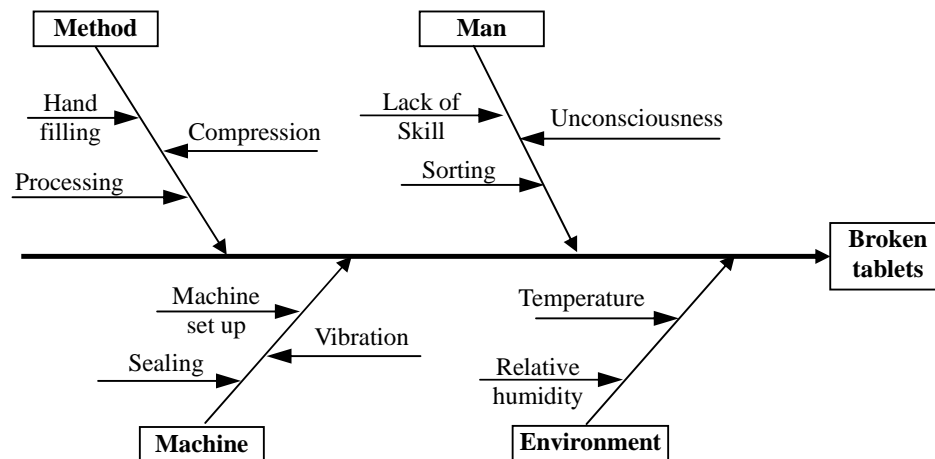


Fig 6. Cause-effect diagram of "broken tablets" problem in blistering

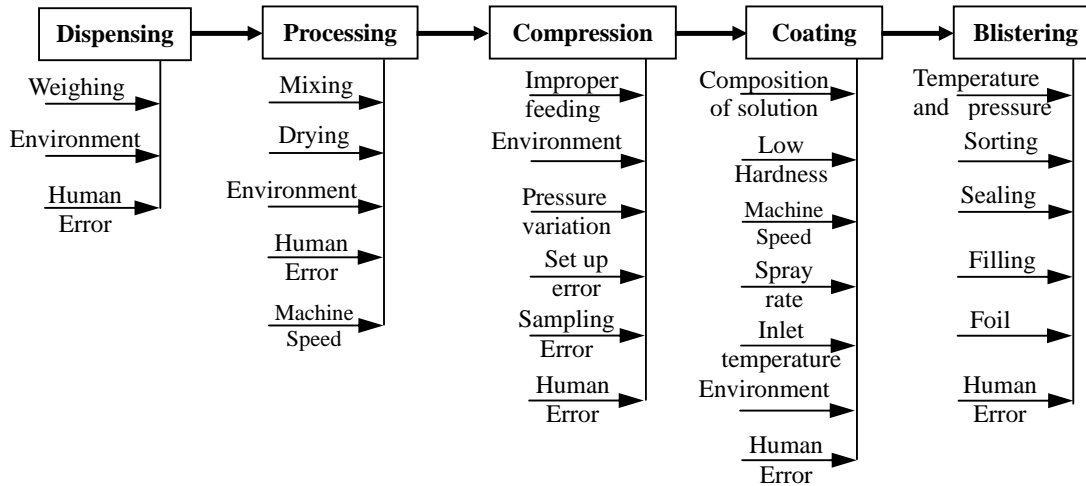


Fig 7. Process flow cause and effect diagram for product defects

Finally, a process flow cause- effect analysis is drawn for the total process to identify exact location of occurrence in complete process. In the manufacturing of the pharmaceutical products, the process is started from the dispensing and completed after packaging. The intermediate stages are processing, compression, coating and blistering. The process flow cause- effect diagram is developed to identify the causes, sub causes and exact location of causes for the defects in tablets. As defects in product may occur any where in the total process, so it is very necessary to identify and eliminate the causes which are responsible for defects in the product. The process flow cause- effect diagram is shown in Fig. 7.

6. CONCLUSIONS

Elimination of defects and maintaining the quality of the pharmaceutical products are very important as it deals with the human life. Pareto and cause effect analysis are two important industrial engineering tools which involve solving the quality problems. In this paper, Pareto and cause effect analysis are used to solve the quality problems for one pharmaceutical product. Causes and location of the causes are identified with the help of these analyses. Then some corrective actions are taken to eliminate causes which ultimately lead to create an adverse effect. Quality of the product is improved through eliminating the causes behind defects. These analyses can be used for other products where quality is one of the important considerations. Some others tools like control chart, check sheet, stratification analysis, scatter diagram etc. can be also used to analyze and solve the quality problem of the pharmaceutical product.

7. REFERENCES

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