THE IDENTIFICATION CRITICAL FAILURE CAUSES OF AMPOULE BY USING FMEA AT QC LAB OF PT. SIG

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Internship Report

2014

ACADEMIC ADVISOR

RECOMMENDATION LETTER

This internship report is prepared and submitted by **Darmansyah Yudi** in partial fulfillment of the requirements for the degree of Bachelor Degree in the Faculty of Engineering has been reviewed and found to have satisfied the requirements for a report fit to be examined.

Cikarang, Indonesia, May 15th, 2015

Ir. Andira, MT

COMPANY'S SUPERVISOR RECOMMENDATION LETTER

Darmansyah Yudi has performed and completed an internship in **PT. Schott Igar Glass**, in partial fulfillment of the requirements for the degree of Bachelor Degree in the Faculty of Engineering. I therefore recommend this report to be examined.

Cikarang, Indonesia, May 15th, 2015

Aulia Abi Herdanu

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ABSTRACT

Quality is the most important aspect that can achieve customer satisfaction for the product that they consumed or used. The company has to fulfill the customer needs and wants, and also any requirement from the first customer must be considered. As the pharmaceutical packaging company that have customer from pharmaceutical company and medical department, they used modern machines and tool during the production and they have special area that called clear zone to select the goods and defect products, also they pack the product in that area, it is to maintain the quality and hygienists of their products. If they cannot maintain the hygienists of their product, it can be big problem for the first customer and even more for the end customer. The author want to define the problem which is the potential causes of defect during the production by using pareto chart and decide the rank in FMEA initial table until get the number of S, O, D. number of S, O, D will be using in calculation of data to define the rank of causes.

The reoccurrence of the problems or failure which causing detected products in PT. SIG can be reduced and prevented by application of root cause analysis and FMEA by solving the problem itself. In pareto, the biggest number of defect occurrence is crack problem; it has occurrence number 97 units during the January, 1th 2014 until July, 28th 2014 and the smallest number of defect occurrence is printing problem that only appear 8 units. The highest RPN will become the main problem of defect product, which is 294, belongs to machine cause.

Keywords: *Control Limit, Quality Checking, Nonconformity, Defected Products, Pareto, Fishbone Diagram, Failure Mode and Effect Analysis (FMEA), Five Whys Analysis*.

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CHAPTER I
INTRODUCTION

1.1 Background

Nowadays, the development of pharmaceutical knowledge can encourage pharmaceutical industry improving enthusiasm of that company itself to compete to their competitor. The most important aspect in most of industry is quality of their product, so that they should maintain and control the quality to make the customers can get the best product. Product with the high quality is product that has characteristics depends on the customer needs and wants.

Main business of PT. SIG is produce pharmaceutical packaging that glass as the raw material of the product. They have three kind of pharmaceutical packaging products, which are Ampoule, Vial, and Horizontal or we known Pipette, and then they also produce complete product such as pipette with the cap that called merchandise product. As the biggest and the one and only pharmaceutical packaging in Indonesia, PT. SIG have to maintain their product quality even they do not have serious competitor with the same industry categories.

Quality is the most important aspect that can achieve customer satisfaction for the product that they consumed or used. The company has to fulfill the customer needs and wants, and also any requirement from the first customer must be considered. Quality can be defined as the consistency in increasing and reducing the variance of the product characteristic to fulfill the specifications and needs of their products, and also to increase customer satisfaction from internal and external.

As the pharmaceutical packaging company that have customer from pharmaceutical company and medical department, they used modern machines and tool during the production and they have special area that called clear zone to select the goods and defect products, also they pack the product in that area, it is to maintain the quality and hygienists of their products. If they cannot maintain the hygienists of their product, it can be big problem for the first customer and even more for the end customer.

Ampoule is a small sealed vial which is used to contain and preserve a sample, usually a solid or liquid. Ampoules are commonly made of glass, although plastic ampoules do exist. Ampoule is one of the product of PT. SIG, during the production quality labor record many defect product of ampoule it self, and it is becoming a big problem for this company.

The Failure Modes and Effects Analysis (FMEA), also known as Failure Modes Effects and Criticality Analysis (FMECA), is a systematic method by which potential failures of a product or process design are identified, analysed and documented. Once identified, the effects of these failures on performance and safety are recognised, and appropriate actions are taken to eliminate or minimise the effects of these failures. An FMEA is a crucial reliability tool that helps avoid costs incurred from product failure and liability.

1.2 Problem Statement

How to identify the failure causes of product of Ampoule?

1.3 Objectives

There are several objective of this research:

- To identify the critical defect causes of Ampoule

1.4 Scope and Limitation

Related to this research that have the several scopes and limitations, it because the short time in doing this research and also the limitation of the resources. So, the scopes and limitations are:

- The research will be conducted in the sort time from September until December at PT. SIG
- This research will discuss about the quality of ampoule and also the identification of defect causes it.
- The observation is will undertake in quality control laboratory of ampoule.
- The researcher will be focusing on critical defect causes.
- The research is solving by MAMFA method.

1.5 Assumption

Ampoule is inspected under normal light conditions with a white or black background and without the aid of magnifying glasses. The distance to the ampoule should be approximately 10 inches.

1.6 Research Outline

Chapter I Introduction

This chapter consists of the background of final project, project identification, objective, and scope.

Chapter II Literature Study

This chapter delivers the previous study about overview of Quality Aspect, Analytical Hierarchy Process (AHP), and Multi Attribute Failure Mode Analysis (MAFMA).

Chapter III Research Methodology

The flow of this final project is explained in this chapter.

Chapter IV Data Collection and Analysis

The data observation is processed and analyzed in this chapter.

Chapter V Conclusion and Recommendation

This chapter will give the conclusion result of this final project, and also recommendation for future research.

In this chapter, the problem and the objectives of this final project have been explained clearly. These are becoming the direction of this final project. After having the direction, it is needed to know the way to solve the problem in order to achieve the objectives. Therefore, some previous studies about related subject are delivered in the next chapter.

CHAPTER II

COMPANY PROFILE

2.0.1 PT. Schott Igar Glass

Delta Silicon Industrial Estate Block L-8 No.6-B. Jln. Meranti III, Lippo Cikarang, Bekasi 17550, Jawa Barat, Indonesia.

Phone : +62-21 – 28640088/89900225 (HUNTING)

Facsimile : +62-21 – 28640066/89900222

Main Business: Schott Product Ampuole, Vial, Pippette, Testube (Packaging Pharmachy).

Schott is a leading international technology-driven group whose base product is special *glass.* SCHOTT is an international technology group with 130 years of experience.

We rank as number one in the world with many of our products, which include components and systems made from specialty glasses and materials. Our core markets are the household appliance, pharmaceuticals, electronics, optics and transportation industries. We are committed to managing our business in a sustainable manner and supporting our employees, society and the environment.

2.1 History of the Company

It all started in Jena, Germany: By establishing the glass technical laboratory SCHOTT & Genossen in 1884 in Jena, Germany, Otto Schott revolutionized the science and technology of glass. He has since then been called the “founder of modern-age glass technology”.

For more than 125 years, SCHOTT has been setting the standard in the special glass industry. Using experience gained in the past, the company creates new ideas for the future. The Ceran glass ceramic cook tops and components for solar systems are only two examples of innovative technology born of tradition

The solidly based SCHOTT Igar Glass operation is backed by the sound financial position of the SCHOTT Group and the Pharmaceutical Packaging Division's global organization, ensuring a steady supply of consistently high quality.

2.2 Vision and Mission

2.2.1 Vision

We make SCHOTT part of everyone's life.

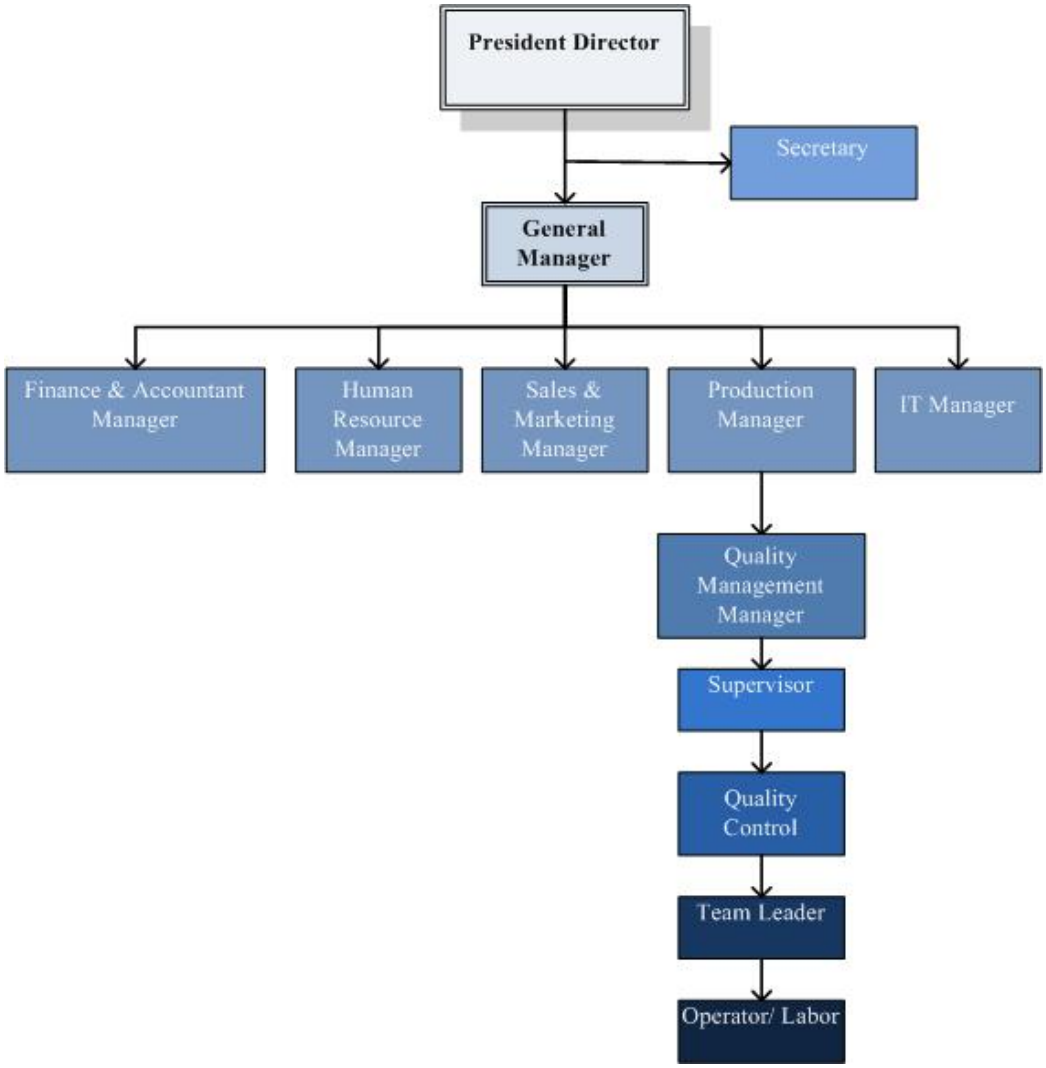
2.2.2 Mission

We profitably enable our customer's success through unique solutions based on our competencies in glass, specialty materials and superior technologies.

2.2.3 Objectives

- Taking on social responsibility.
- Taking care of our environment.
- Improve Quality Technology on the Glass.
- Make sure the consumers safe when use our product.
- Have good relation between Schott and other enterprise.

2.3 Organizational Chart



2.4 Core Organization Activities

PT. Igar SCHOTT Glass is a pharmaceutical company which is the sole producer of packaging for pharmaceutical packaging products in Indonesia. Products PT. SCHOTT Glass Igar intended for pharmaceutical companies as drug storage. So it takes a high packaging costs and the right distribution channels to customers that ordered goods to the customer is not in a state of disrepair, broken, and bacterial contamination.

Good distribution channel requires a distribution system that is controlled because the distribution system is a part of marketing that is flexible so it can be easily influenced by external factors.

PT. SCHOTT Glass Igar have a direct distribution channel, where the goods ordered by the customer delivered directly by PT. SCHOTT Glass Igar warehouse to the customer by using the transport services (forwarder). PT. SCHOTT Glass Igar have established a system to regulate the distribution of activity in the SOI (Standard Operating in structure) Publishing and Distribution which has two standards are standards before shipment of goods and After delivery of the goods. Each system is designed by an organization there are defects in the absence of standardization in the distribution system. To see the deficiencies in the system of distribution of PT. SCHOTT Glass Igar it is necessary to review the control of the distribution system in order to do repairs that provide convenience to minimize errors that may occur in the system.

The activities Schott is a test that is held every year on employee quality field. The purpose of the activity is that employees become more careful in making measurements of the product that has been in production by Schott. Activities such as making measurements with vials or Ampoule that were available and measurement tools that have been determined. With so each employee will be recorded and will be available as a result the average measurement of the employee is suitable or harm is still far from the expected results. If further than expected, then the employee should be repeated again until the appropriate measurement. It is an important means to improve the quality of production.

On a Quality Management division there is checks of the size of the vial and ampoule along with tray or storage. Because the field of pharmaceutical Packaging Schott then must check the size of the vial or ampoule is already in line with that required by the customer and according to standard or not appropriate. This is because that when making deliveries to the consumer, the goods of Schott did not fall or have no complaints, so it is important to check these things first. There was also an examination of the sample. Sometimes the need for comparing the quality of the product by giving samples to the quality management section. The goal is to be able to see the materials in use, learn to improve the quality of production and ensure that the sample had either.

Schott also do a lot of activities such as audits, usually Schott will send appropriate representatives to conduct an audit firm to another. The goal is to review about the company, how the production system and how the system is working in a company where Schott cooperation. Likewise with other companies that perform the audit to Schott Igar Glass. It will usually look around the place of production to the production of how systems work. The purpose of it is rather the other companies can trust the quality produced by Schott and still cooperate with PT. Schott.

2.5 Product & Service

There is a broad range of products and services that is provided by Schott:

Pharmaceutical Packaging

PACKAGING ARTIST

SCHOTT Pharmaceutical Systems is one of the world's leading manufacturers of specialty glass tubing and primary packaging for the pharmaceutical industry and is capable of serving customers all over the world. The five production sites for glass tubing and 16 pharmaceutical packaging facilities are divided across four continents and are able to offer the same consistent quality, reliability and security of supply combined with local service. SCHOTT Pharmaceutical Packaging manufactures more than 9 billion syringes, vials, ampoules, cartridges and

specialty articles made of glass tubing or polymers. Cartridges are pre-fillable glass cylinders that are used in pen injection systems.

Schott Indonesia is the only manufacturer that produces pharmaceutical packaging such as Vial, Ampoule and Pippete which has been believed by the entire pharmacy in Indonesia. Schott Igar Glass has worked with many companies such as Kimia Farma, L'oreal, and Mustikaratu. They believe Schott to produce medicine and cosmetic packaging that is safe and not contaminated with germs.

GLASS-CERAMIC COOKTOP PANELS FROM SCHOTT

SCHOTT is the inventor of the black glass-ceramic cooktop panel, a product which the company has been manufacturing with the help of an advanced manufacturing technique under the brand name SCHOTT CERAN® since 1971. Glass-ceramic cooktop panels are not limited to any specific type of heating technology. They can be used in conventional electric ranges as well as induction and gas ranges. But you can only be certain that you are cooking on the original if you can see the well-known SCHOTT CERAN® logo

Anti-reflective glass covers and special optical filters provide a clearer view of the instruments.

SCHOTT researchers already have their sights set on the next innovation. They are developing a special, extremely hard glass laminate for the inside panes of cabin windows that is extremely resistant to breakage and scratches. Unlike the plastics that are currently being used, it will be thinner and lighter. The new glass laminate also meets all of the safety requirements for cabins that are of relevance to aviation as well as to all of the fire protection requirements. This material is also well-suited for use in the transparent partitions inside cabins and could therefore offer aircraft engineers new design possibilities in the future.

2.6 Review on the organization growth and trend

Better Faster Safer

With its new plant site, the Indonesian manufacturer of pharmaceutical packaging, SCHOTT Igar Glass, is setting its sights on the quality and growth markets of the Asian-Pacific region.

The trend towards higher quality is as strong in Asian-Pacific pharmaceutical markets as it is elsewhere around the world.We expect a growing interest in high-quality pharmaceutical packaging in this region, predicts the President of SCHOTT Igar Glass. Globalization has necessitated greater efforts on the part of all market participants in the field of healthcare.

This also applies to the some 200 pharmaceutical companies in Indonesia. They are increasingly having to cope with international standards such as the “Good Manufacturing Practices” (GMP) prescribed by national health authorities and the World Health Organization (WHO). These guidelines regulate the health-, quality- and safety-conscious production of drugs. In short, they set the compulsory quality standards on an international level for progressive pharmaceutical companies and their supplier.This means if you want to be a global player, you have to meet these high standards. The pharmaceutical packaging market in Asia is still dominated by mass-produced articles and thus low prices.

0.2Setting performance standards

Special glass tubing is used to manufacture high-quality pharmaceutical packaging products on 60 production lines.

In three shifts, SCHOTT Igar Glass manufactures some 500 million vials, ampoules, pipettes and special articles for the pharmaceutical market every year. Globally operating companies such as Roche, Aventis and Pharmacia are among the company’s customers, as are “local heroes” like Biofarma and Harsen. In its quality segment, which is growing to the same extent as the much larger overall market, SCHOTT Igar Glass has to hold its own against several regional

competitors. Here the Indonesian subsidiary benefits from its parent company, SCHOTT, which, as a true global player, can provide the necessary resources. The strategy is clear: quality is the key to success on the market. And SCHOTT has been willing to invest several million euro to underscore its commitment. A bigger and more modern factory was built near Jakarta, and the equipment and employees from SCHOTT Igar Glass were relocated to the new site – all in two months.

CHAPTER III
LITERATURE STUDY

2.1. Pareto Chart and Analysis

Pareto chart is a type of chart which purpose is to emphasize the most important thing among a set of factors by representing individual values of a set of factors in descending order (Frank M. Gryna, 2007). In Pareto Chart exists two type of graph which represents the connection between the value of each individual and the cumulative percentage of the factors which exists, they are bar graph and line graph. The bar graph will shows the individual values of the factors in the graph while the line graph shows the cumulative percentage of the factors. Since in Pareto Chart exists two type of graphs, there also exists two information of value which stated on both sides' x-axis of the chart of the Pareto Chart, the left x-axis will shows the frequency of occurrence or the individual value of each factors and the right x-axis shows the value of the cumulative percentage of the factors. In making the Pareto chart it is mandatory to order the factors from the one which has the biggest individual value to the smallest one. While Pareto Analysis is a systematic technique which is used to solve a problem by solving the cause of the problem based on its individual value (the one with bigger value is more important to be solved first).

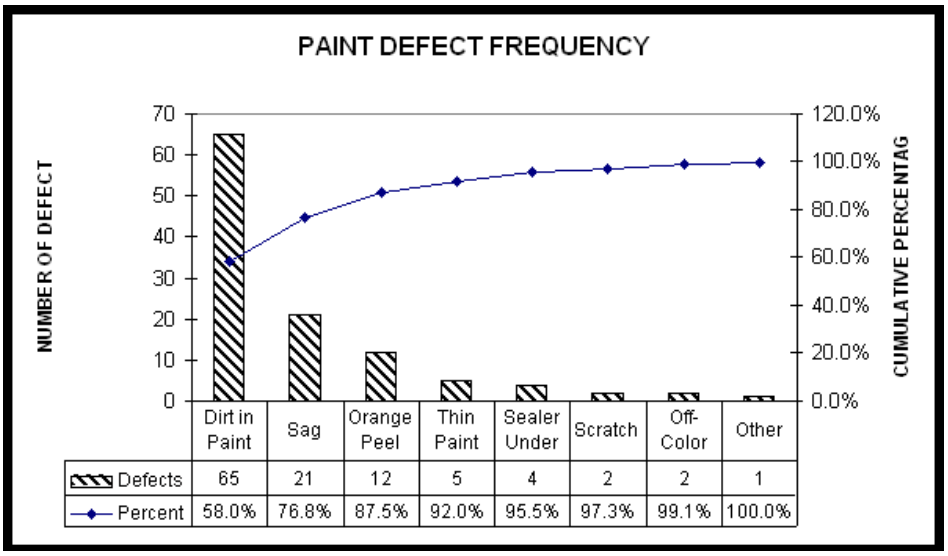


Figure 2.0.1 Pareto Chart (Source: www.moresteam.com)

2.2. Failure Mode and Effect Analysis (FMEA)

FMEA is a tool use to detect a part or a process with failure risk in fulfilling a specific requirement, created with defect or different and those failure modes will result to the customer when the failure mode is not prevented or corrected. (Crow, 2002).

FMEA is a method use to analysis and identify:

1. All potential failures that can happen in a system
2. The effects of the failure in the system and how to fix or minimize the failures or effects in the system (Corrective and minimize action taken normally will be based on rank from severity and probability and failure)

FMEA is usually conducted during the conceptual stages and beginning stages of design from a system to find out the possibilities of failures and what are the corrective actions to be taken to overcome those failures so that the potential failures can be minimize in all stages of the process. (Lange, 2001)

FMEA can variant on different detailed level reported, all of that are based on the details needed and the availability of the information. As the development proceeds, critical considerations are added and became Failure, Mode, Effects and Critically Analysis and FMECA. There are many variations in the industry where FMEA analysis can be implemented. A set of standard and regulation had been developed to determine the needs for analysis and every organization can have different approach when conducting the analysis.

Definitions according to the ranking from different terminologies of FMEA are as follows:

1. Potential effect is effect felt or experience by the end user.
2. Potential mode is failure or defect in a design that cause the unexpected defect in the system.
3. Potential cause from a failure is weaknesses in design and changes in variables that affect the process and resulted defective products.

4. *Severity (S)* is subjective estimation on how bad the next recipient or till the end customer will be affected from those failures. It shows the effects from the failures impacting the conditions. Table 2.1 will shows how the rating for severity is done.

Table 2.1 Severity Rating

Severity Ratings	
Ratings	**Meaning**
1	No Effect
2	Very minor (only noticed by discriminating customer)
3	Minor
4/5/6	Moderate (most customers are annoyed)
7/8	High
9/10	Very high and hazardous (customers angered)

(Source: Gaspersz, 2002)

5. *Occurrence (O)* is estimation on probabilities or chances that the affect will take place and resulting failure mode that causes a certain consequences. Table 2.2 will show how the rating for occurrence can be done with some certain guideline to be followed but it can vary depends on the user.

Table 2.2Occurrence Rating

Occurrence Ratings		
Ratings	**Meaning**	**Frequency**
1	No known occurrences on similar products or process	0 in 3000
2/3	Low (relatively few failures)	1 in 3000
4/5/6	Moderate (occasional failures)	3 in 3000
7/8	High (repeated failures)	5 in 3000
9/10	Very high (failure is almost inevitable)	$\geq$ 7 in 3000

(Source: Gaspersz, 2002)

6. *Detectability (D)* is subjective estimation of the effectiveness and methods for prevention or detection.

Table 2.3 Detectability Rating

Detection Ratings		
Ratings	**Meaning**	**Frequency**
1	Certain - failure will be caught on test, no chance that the cause to reoccur.	0 in 3000
2/3	High (causes a loss of primary function), the chance of the cause reoccurrence is very low.	1 in 3000
4/5/6	Moderate, there is a possibility that the causes may reoccur.	3 in 3000
7/8	Low, the detection method is not very effective, the cause may still reoccur.	5 in 3000
9/10	Fault will be passed to customer undetected (detection method is not effective), the reoccurrence level of the causes is very high	≥ 7 in 3000

(Source: Gaspersz, 2002)

7. *Risk Priority Number (RPN)* is the result from the product multiplication between the ratings of *severity, detectability, and occurrence*.
   RPN = (S) x (D) x (O) (2-1)

2.6.1. Benefits of FMEA

The benefits from FMEA are:

- The final product should be "safe", FMEA helps designers to identify and eliminate or control failure risk, minimize from the estimation on system and its users.
- Increase of accuracy from estimation of the chances of failure that will be develop in the future, in particular also to obtained data from reliability opportunities using FMEA.
- *Reliability* of the product will increase
  Time use to do a design will be decreasedthrough identification and repair of problems.

2.6.2. FMEA Process

FMEA process is an analytical techniques used by manufacturing team that is responsible to assure that possibility of failure ways and to find the cause related to the failure with consideration and put into a proper data form, FMEA is a summary of ideas from the engineering team (including analysis from items that are going according to the past experience and ideas) as the process is develop.

FMEA process:

- Identify potential product that related to the failure process
- Forecasting the effect to the potential consumers resulted from the failure
- Identify the possible cause in a chain process and identify variables in the process and focus on the restraint to minimize failure or detect other failure modes
- Develop a ranking list from the potential failure modes, this determine the system's priority as consideration on which failure needed more urgency to be corrected
- Keep record of the outcome results from the production process or assembly process

2.6.3. Risk Priority Numbers in FMEA

Risk Priority Number (RPN) method is a technique use to analyze risk related with the potential problems that had been identified during the tabulation of FMEA (Stamatis, 1995)

An FMEA can be use to identify the potential failure ways for a product or a process. RPN method then needed the analysis from the team to use the past experiences and engineering decision to give rank on each of the potential cause according to the rating scale as follows:

- *Severity*, scale that rank severity from the potential effect of failure
- *Occurrence*, scale that rank the possibility of the occurrence of the failure

- *Detection*, scale that rank the possibility of detection problem before arriving at the end user or consumers

Once all of the rating is given, RPN value from each of the failure modes are calculated with the formula below:

RPN = *Severity x Occurrence x Detection* (2-2)

The RPN value from each potential problems can then be use to compare the causes identified during the analysis. In general, RPN falls between the specified boundary, corrective action can be suggested or done to reduce risk. While using *risk assessment* technique, it is very important to know that the level of RPN is relative towards a certain analysis (it is done with a set of scale ranking and team analysis that aims to derive with consistent ranking for all the problems cause that are identified during the analysis). For that, an RPN in an analysis can be compare with the other RPN in the same analysis as well, but it might not be suggested to compare the RPN from one analysis to other RPN analysis.

Even thou there are many types and standard of FMEA, FMEA is consist of a set of common procedure. In general, FMEA analysis is affected by the team that is working in a cross function way at each stage that varies on the time of design. Development process in general consists of the following:

- *Item or Process*, identify item or process that will be use as subject from the analysis. Including few study on the design and reliability characteristics
- *Function*, identify the functions where the item or process are expected to be involve
- *Failures,* identify the known and potential failures that can prevent or minimized the performance of the item or process to work as it's function
- *Failure effect,* identify the known and potential effect that can appear in each of those failures
- *Failure cause,* identify the known and potential cause for each failure
- *Current Control,* examine the control mechanism that is available to eliminate or minimize the occurrence of the failure

- *Recommended action,* identify the corrective action that needed to be implemented in order to eliminate or minimize risk and continued with giving recommended action
- *Prioritize issues,*Prioritize corrective action that has to be done according to the consistency standard that had been decided by the company. RPN rank is a common method use for prioritizing
- *Other Details,* depending on a certain situation and leads for doing the analysis that can be adapted by the company, other information may be taken up as consideration while doing the analysis, such as operational way when failure occurs

Report, develop a report from the analysis in a standard format given by the company. In general it will be in table format. As addition to the report, diagram can be added to illustrate item or process that was use as subject from the analysis

Failure Mode and Effect Analysis firstly introduced and used in the 1960s. In the first introduction of this methodology, this methodology is known as Failure Mode Effect and Critical Analysis (FMECA) or FMEA. In the beginning it is used as a formal system in aerospace industry and defense system. Since the beginning of 1970s, FMEA technique was spreading to the other industry. Then in the middle of 1970s, the methodology then is adopted in automotive industry as a tool to identifying serious potential regulatory and safety issues. Then in the 1993, an FMEA standard is published and applied in automotive industries. Although this methodology initially developed and used in the military, this methodology nowadays is widely used in variety industries including food and beverages, services, plastics, healthcare, software development, and etc.

Failure Mode and Effect Analysis or generally known as FMEA is a risk assessment tool which is used to identify the possible ways in which a product or a process might fail with the main purpose of improving the existing product or process and preventing the reoccurrence of the failures (Denny Nurkertamanda, 2009). FMEA also works to identify the potential failure modes that may happen in a product or process before the failure happen, this tool works by identifying the possible failures that may happen, then avoid the possible failures that may happen by providing corrective and preventive actions for the possible failures that may happen (Frank M. Gryna, 2007). By applying FMEA, every occasion that has direct contribution to the failure is identified. Failure Mode and Effect Analysis (FMEA) works as a step-by-step approach for identifying all possible failures in

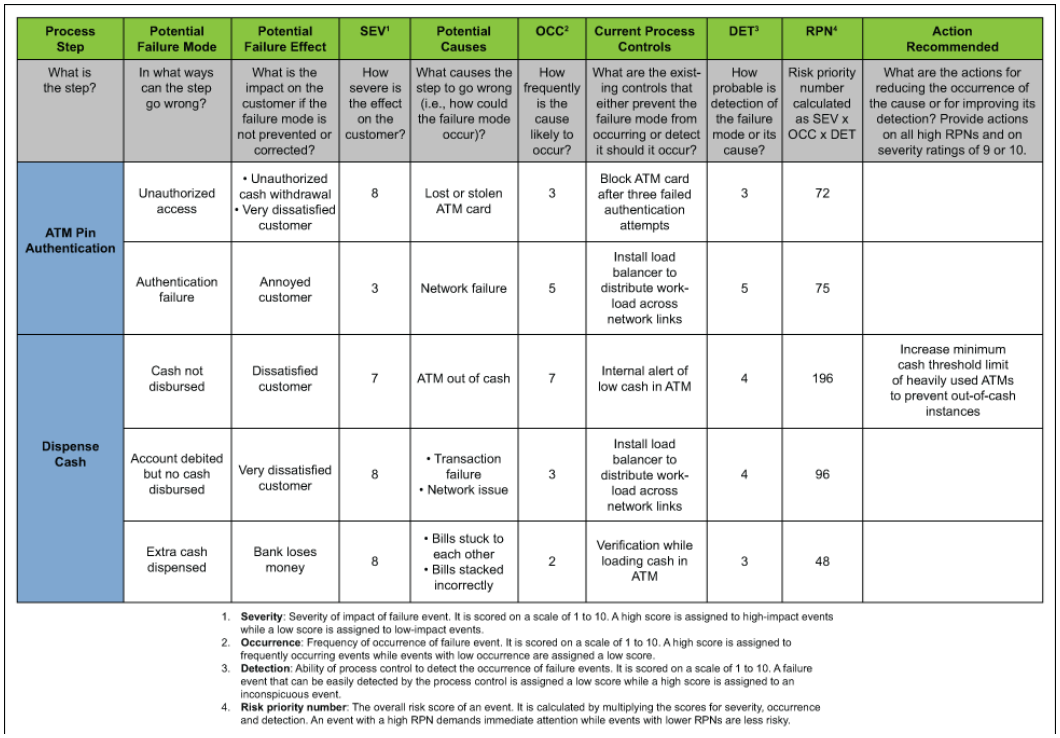
a design, a manufacturing or assembly process, a product or a service by prioritizing the failure according to how big their consequences are, how frequent they occur and how easily they can be detected. The purpose of FMEA is to reduce or eliminate failures which take place in a system starting with the highest priority ones.

In using FMEA, it is assumed that there are three criteria that are being considered; *severity, occurrence, and detection.* In applying FMEA, all the three factors have the same degree of importance. All the three criteria of FMEA have several values in which the values indicate the rate of the *severity, occurrence,* and *detection* of the failure that happen in the system. Severity Ratings indicates the seriousness of the effect of the failure, the Occurrence Ratings indicates the probability or estimated number of frequencies that the failures will occur in the system or product with the given cause, the occurrence ratings will be decided based on the experience. While the Detection Ratings indicates the probability that the failure will be discovered or detected in the system or product, after given a series of control to prevent the failure modes. After all the criteria have their own value, all the criteria's value will be multiplied, and then the *risk priority number (RPN)* will be obtained. The RPN indicates the rank or the order of which problem needed to be solved first in order to make the system become efficient.

In conducting FMEA, there are several general steps that can be followed:

- The first step of conducting FMEA is identifying the steps of a process, or parts of a product in which the failures may occur.
- The next step is the identification of the failures modes.
- The third step is to identify the failure effects, which is the result of the failure.
- After the effect of the failure is identified, the severity rank of the failure is given. The rank of the severity ratings is using the scale of one to ten scale with one is equal to the least severe and ten is for the most severe.
- The next step is identifying the potential causes of the failure.
- The sixth step is assessing the occurrence ratings. The rank of the occurrence ratings is using the scale of one to ten scale with one is equal to no occurrence of similar failure in other process or product and ten is for very high occurrence of the failure.
- The next step is to define the controls or action to prevent the failure to reoccur or being happen and detected in the future.

- Then the assessment of the detection of the failure supposed to be done. In assessing the detection ratings the scale of one to ten scales is used, with one is equal to the failure will certainly being detected and ten is for the identification of the failure will be passed to the customer undetected or the customer will not realize that the failure happen in the process or the product.
- Next is calculating the risk priority number or RPN. The risk priority number will be calculated using the formula of *RPN = severity * occurrence * detection.*
- After the risk priority number is gained, the next step is to react to the result of the risk priority number by solving the failure mode of a product or a process which has the highest result of the risk priority number.
- After an action in order to react to the failure, recalculation of the RPN to confirm if the failure risk has been reduced should be conducted.



Process Step	Potential Failure Mode	Potential Failure Effect	SEV[1]	Potential Causes	OCC[2]	Current Process Controls	DET[3]	RPN[4]	Action Recommended
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.
ATM Pin Authentication	Unauthorized access	• Unauthorized cash withdrawal • Very dissatisfied customer	8	Lost or stolen ATM card	3	Block ATM card after three failed authentication attempts	3	72	
	Authentication failure	Annoyed customer	3	Network failure	5	Install load balancer to distribute work-load across network links	5	75	
Dispense Cash	Cash not disbursed	Dissatisfied customer	7	ATM out of cash	7	Internal alert of low cash in ATM	4	196	Increase minimum cash threshold limit of heavily used ATMs to prevent out-of-cash instances
	Account debited but no cash disbursed	Very dissatisfied customer	8	• Transaction failure • Network issue	3	Install load balancer to distribute work-load across network links	4	96	
	Extra cash dispensed	Bank loses money	8	• Bills stuck to each other • Bills stacked incorrectly	2	Verification while loading cash in ATM	3	48	

1. **Severity**: Severity of impact of failure event. It is scored on a scale of 1 to 10. A high score is assigned to high-impact events while a low score is assigned to low-impact events.
2. **Occurrence**: Frequency of occurrence of failure event. It is scored on a scale of 1 to 10. A high score is assigned to frequently occurring events while events with low occurrence are assigned a low score.
3. **Detection**: Ability of process control to detect the occurrence of failure events. It is scored on a scale of 1 to 10. A failure event that can be easily detected by the process control is assigned a low score while a high score is assigned to an inconspicuous event.
4. **Risk priority number**: The overall risk score of an event. It is calculated by multiplying the scores for severity, occurrence and detection. An event with a high RPN demands immediate attention while events with lower RPNs are less risky.

Figure 2.0.2 FMEA Diagram Example (Source : Google.com)

2.3. Fishbone Diagram

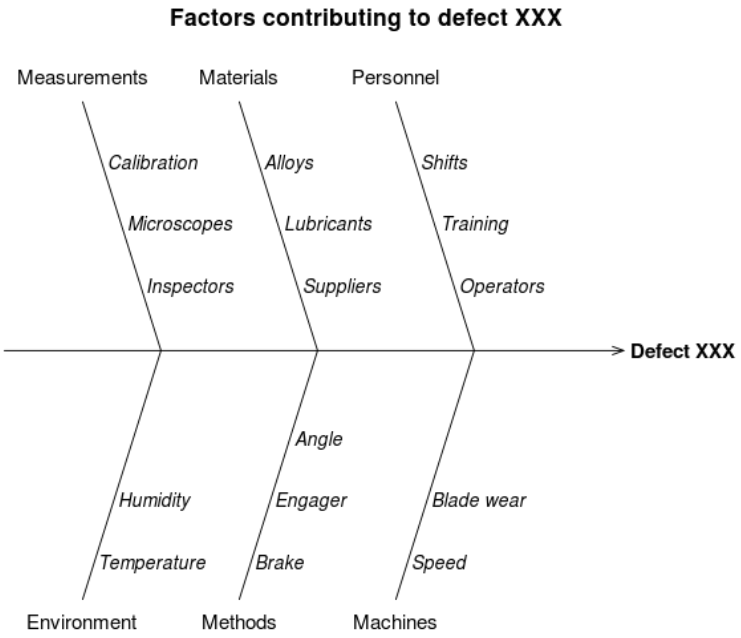


Figure 2.0.3 Fishbone Diagram (Source : Google.com)

Ishikawa diagrams or also know as cause-effect diagram is a diagram which is used to show the causes of a specific event. This diagram was created by Kaoru Ishikawa in 1968. Commonly, this diagram is used as an identification of possible causes for a problem with the purposes of preventing defect or variation occurrences and supports the process of product design (Cindy Chandra, 2014). In the cause-effect diagram, the causes are usually grouped into six major categories which are;

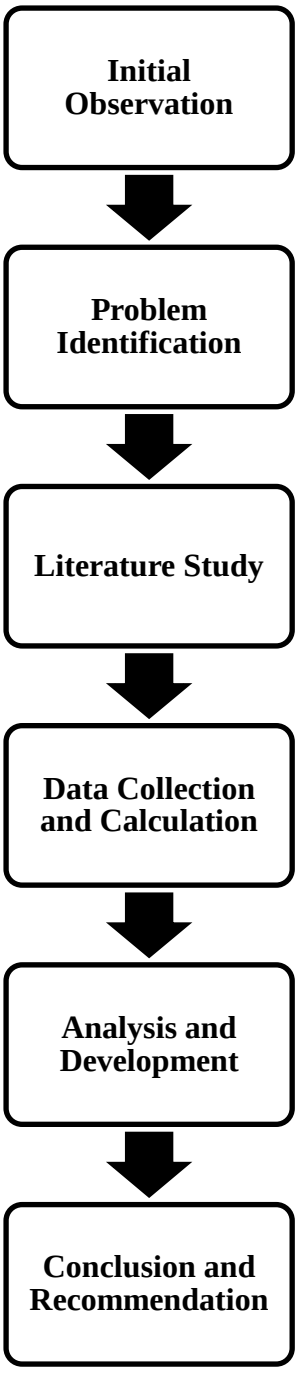
- People; includes those who involve in the procedure.
- Methods; how the procedure is performed and its requirements in preceding the procedure.
- Machines; all equipments needed to accomplish the job, include all tools, computers, software, etc.
- Materials; include all raw materials, parts, etc which are used to produce the final product.
- Measurements; all the data from the process which is used to evaluate its quality.
- Environments; include the situations, conditions, location, and culture where the process took place.

As a causal diagram which reflect the relation between the result and its causes, in making the causal diagram, the first step that must be done is deciding the effect that wanted to be solved through this method, after the effect or the problem wanted to be discussed is decided, put the problem on the right side of the diagram. The next step is deciding some major categories which causing the problem (methods, machines, materials, people or human resources, environments, measurements) and write them down on the main arrow's branches. After the major categories has been decided, think of the causes why the major categories can support the occurrence of the main problem, then write the cause of the problem on the diagram as a new branch of the major category. After the cause has been discovered, keep asking the "Why?" question to find out the sub-causes and write them down as the branches of the cause of the problem. The more "Why?" questions are asked and being answered, the deeper the level of causes will be obtained while the branches in the diagram indicates the relationship between the effect or the problem with its causes, but in obtaining the causes of the problem, it is important to be objective despite of being subjective.

CHAPTER IV

RESEARSC METHODOLOGY

In this chapter discuss about the methodology of this research, there several steps that will conduct for this research. The research method can be described through figure 3.1, and for the following section the outhor will explain more for each steps and method of this research.



Initial Observation

- Gather data from current condition
- Observation from the data

Problem Identification

- Analyze the possible risks
- Identify the risks probability

Literature Study

- Pareto Diagram
- FMEA

Data Collection and Calculation

- Phase I : Data gathering and observation
- Phase II : Data tabulation and calculation

Analysis and Development

- Analyze possible risks
- Develop FMEA model

Conclusion and Recommendation

- Conclusion.
- Recommendation and future research.

3.1 Initial Observation

The initial observation is conducted in the Quality Control Laboratory of PT. SIG. The author gathers current data by done direct observation and collect the general information by interview several staff and also operator. After the data has been collected this can be quantitative or qualitative data. The purpose of initial observation is to collect the data in the current condition of company.

3.2 Problem Identification

The problems that are occurred should be marked and then identified. Understanding the main problem and finding what method should be used are also become the problems that have to be solved.

3.3 Literature Study

Literature study must be conducted prior to the stage of data collection and calculation, and also stage of analyze and develop data. Literature study will be helpful to determine what kind of data should be gathered, calculate the data, and what method should be used. In this research, the methods have been used by pareto chart and Failure Mode and Effect Analysis.

3.4 Data Collection and Calculation

3.4.1 Data Collection

Data collection is done by do direct observation at the company, which is in quality control laboratory and also interview with the quality control and production staff. Data which collected by the author such as:

1. Company profile
2. Organization structure
3. Current condition
4. Types of the product
5. Production process / Flow chart
6. Data inspection of Quality control staff
7. Data collection of FMEA table

3.4.2 Data Tabulation and Calculation

In this step, the author want to define the problem which is the potential causes of defect during the production by using pareto chart and decide the rank in FMEA initial table until get the number of S, O, D. number of S, O, D will be using in calculation of data to define the rank of causes.

3.4.2.1 Decide S, O, D Rank

In this step, the author do the analysis and explanation for each rank that already given, such as for the effect, cause, even control that have been done. The purpose of this analysis is to make each rank that given has strong basic and reason.

3.4.2.2 Calculate the RPN

Risk Priority Number (RPN) is the result of multiplication from three criteria in FMEA which are Severity (S), Occurrence (O) and Detectability (D). The highest values of RPN indicate to the most critical process and need to be solved.

3.5 Analysis

After having data collection and calculation, the crucial criteria that have to be fixed should be determined. The criteria that are found should be analyzed and fixed.

Finally, development of those criteria should be conducted to the company. By conducting the development, the company can always increase their performance.

3.6 Conclusion and Analysis

Conclusion will affirm whether the result of analysis and development stage achieve the objectives or not. After concluding, recommendation for future research should be provided.

CHAPTER V
DATA CALCULATION AND ANALYSIS

4.1 Data Collection

First of all, it begins with flow process chart to know the step of the production of this product which is ampoule, the flow process chart shown in figure 4.1. The production process start by prepared the material tools and the extended yellow map, and then the machine setup by setup man until the machine ready to use for mass production, the process begin by load the material which is the tube glass to machine by the operator, the operator have to follow the procedure on the Standard Operational Procedure (SOP) to check BFT and also for in process control by random sampling. If the ampoules are not in specification, the operator has to inform the setup man to re-setup the machine, but if the ampoules still in the specific, the production have to continue and the One Point Cut (OPC) and Dot Dimension is controlled and also automatically inspected by TM 95 Camera by Quality Engineering staff. Then the ampoule ready for annealing process, annealing is a process of slowly cooling hot glass to relieve internal stresses after it was formed. The process may be carried out in a temperature-controlled kiln known as a lehr. Glass which has not been annealed is liable to crack or shatter when subjected to a relatively small temperature change or mechanical shock. Annealing glass is critical to its durability. If glass is not annealed, it will retain many of the thermal stresses caused by quenching and significantly decrease the overall strength of the glass.

Ampoule inspect again visually by Packer Inspector (PI) in line before PI put it into innerbox, and it is called pre-packing stage, if the visual aspect is not in specification the ampoule is rejected, and the see the cumulative rejection if more than target the selector packer has to inform operator even cumulative rejection is has to be less than the target and the operator inform the setup man to reset the machine, but if not more than the target the packer inspector prepare the innerbox for QC inspection by the QC checker, then if the defect is bigger than AQL, so ampoules in the innerbox is reject and will not be released.

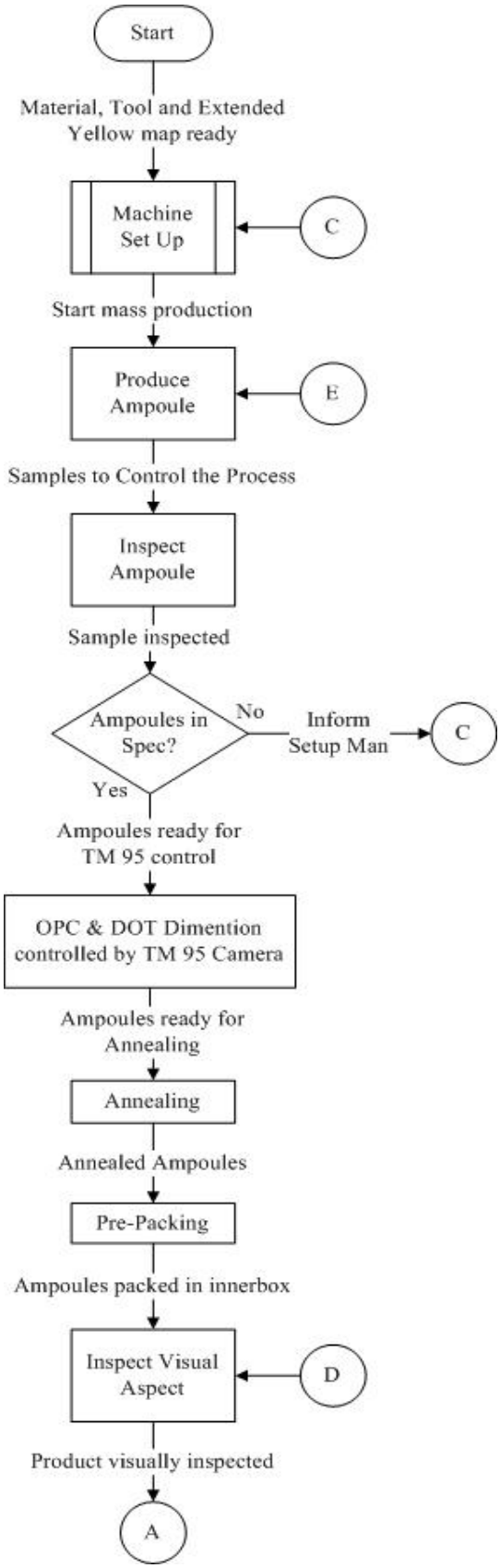


Figure 4.1 Flow Process Chart

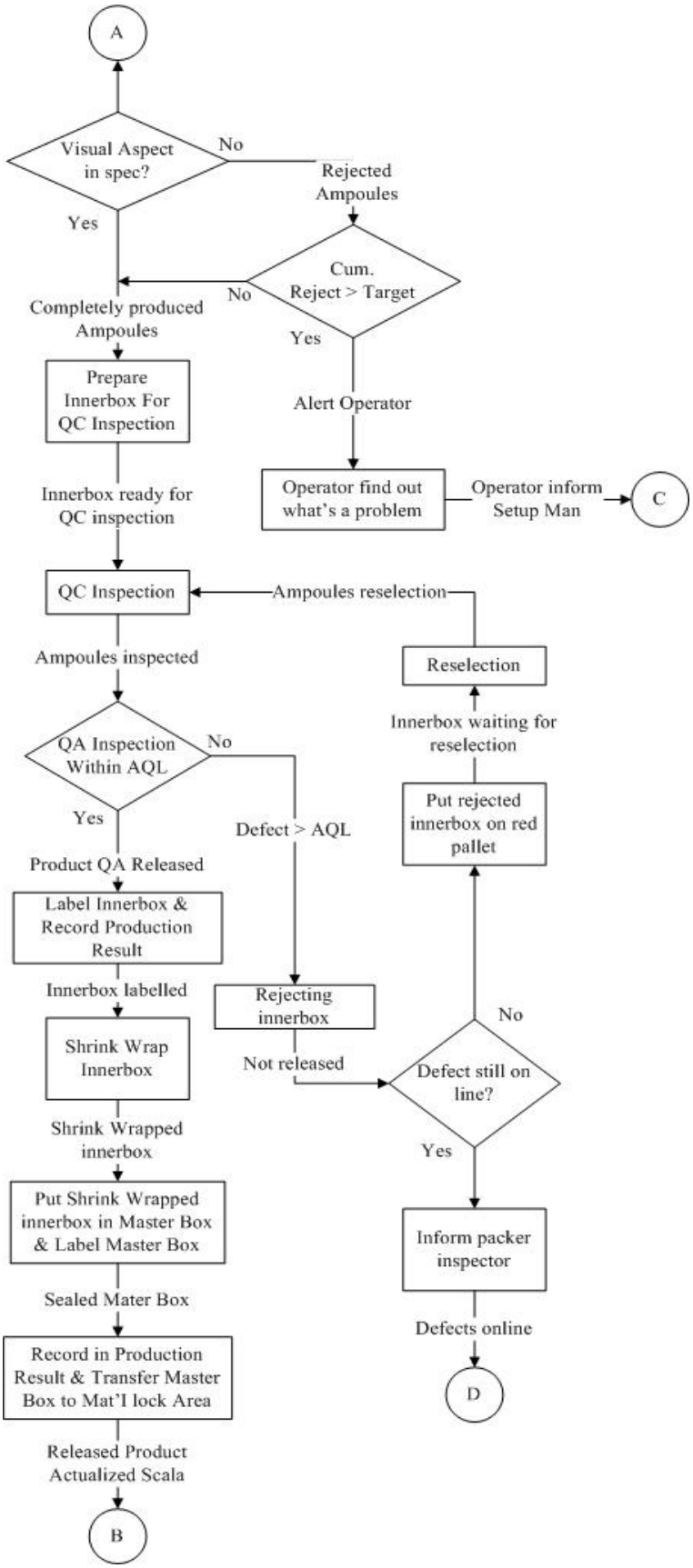


Figure 4.2 Flow Process Chart (Continued)

If the defect of ampoule is still on line the QC checker will inform the packer inspector that defect on line and do the visual inspection and also inform to the setup man, but if the rejection innerbox is off line then put it on the red pallet for reselection by packer inspector, after that QC checker will be inspected again the ampoules reselected.

On the other hand, if QA inspection within AQL so the product QA will be released and make sure that packer inspector put the label on the innerbox and also record the result of production, after the innerbox is labeled then packer will shrink wrap the innerbox, the shrink wrap process also has follow the SOP and packer put all the shrink wrapped innerbox into the master box then seal the master box, then the packer record the production result after the master box is transferred to the Mat'l Lock Area.

The quantity of ampoules are released in scale, if the order quantity is fulfilled so Yellow Map is completed already by operator, packer inspector, packer, QC checker and the production supervisor, it is mean the production flow is finished, but the order quantity is not fulfilled, then the mass production of ampoules have to repeat to fulfill the demand.

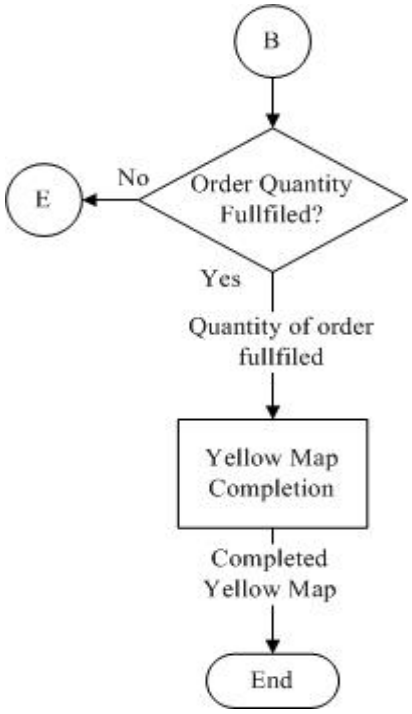


Figure 4.0.3 Flow Process Chart (Continued)

After the production process is done and the product have been delivered to customers, the product of ampoules will inspected again by customer, if they find defect on the product, they will make a complaint letter to management complaint department of PT. SIG and the complaint management staff will be record the data of complaint based on the letter that received, the data shown in table in appendix.

Tabel 4.1 Summary Defect List of Ampoules

Defect Classification	Crack	Glass Particle	Deformation	Scratches	Air bubbles	Printing
Number of Defect	97	91	42	34	29	8
Unit Percentage	32%	30%	14%	11%	10%	3%
Commulated Percentage	32%	62%	76%	88%	97%	100%

Based on the data of complaint the author return into table 4.1 above, data is came from the customer complaint and nonconformity or defect list since January, 1th 2014 until July, 28th 2014, and total have been produced in the meantime is 6794 products of ampoules. Actually there are many type of defect, but then it is chosen 6 types of defect which is very often appear during the production and from the customer complaint, the six types of them already classify into Crack, Glass Particle, Deformed, Scratches, Air Bubbles, and printing that have number of defect of each is 97, 91, 42, 34, 29 and 8 products of ampoules. After the calculation the defect percentage come out with the number 4,43% more bigger than the AQL number is 4%, which is the defect already out of the control limit as shown in the figure 4.4 below.

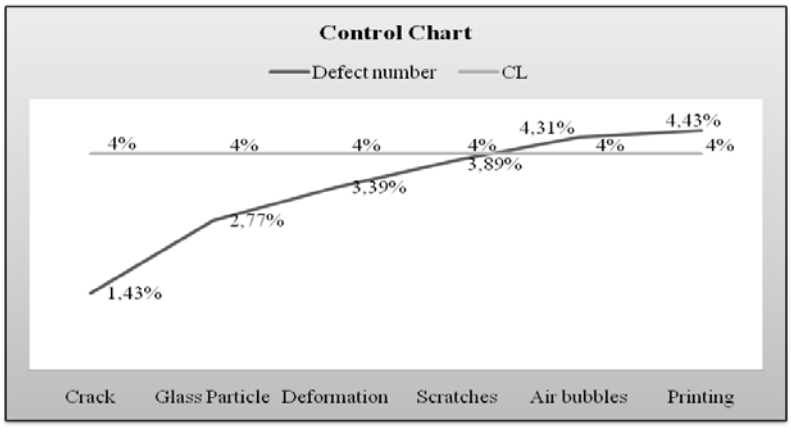


Figure 4.4 Control Chart

The graphic below it can be seen the biggest number of defect occurrence is crack problem; it has occurrence number 97 units during the January, 1th 2014 until July, 28th 2014 and the smallest number of defect occurrence is printing problem that only appear 8 units. So the critical defect type that has to be solved is the crack problem which excessively turns up.

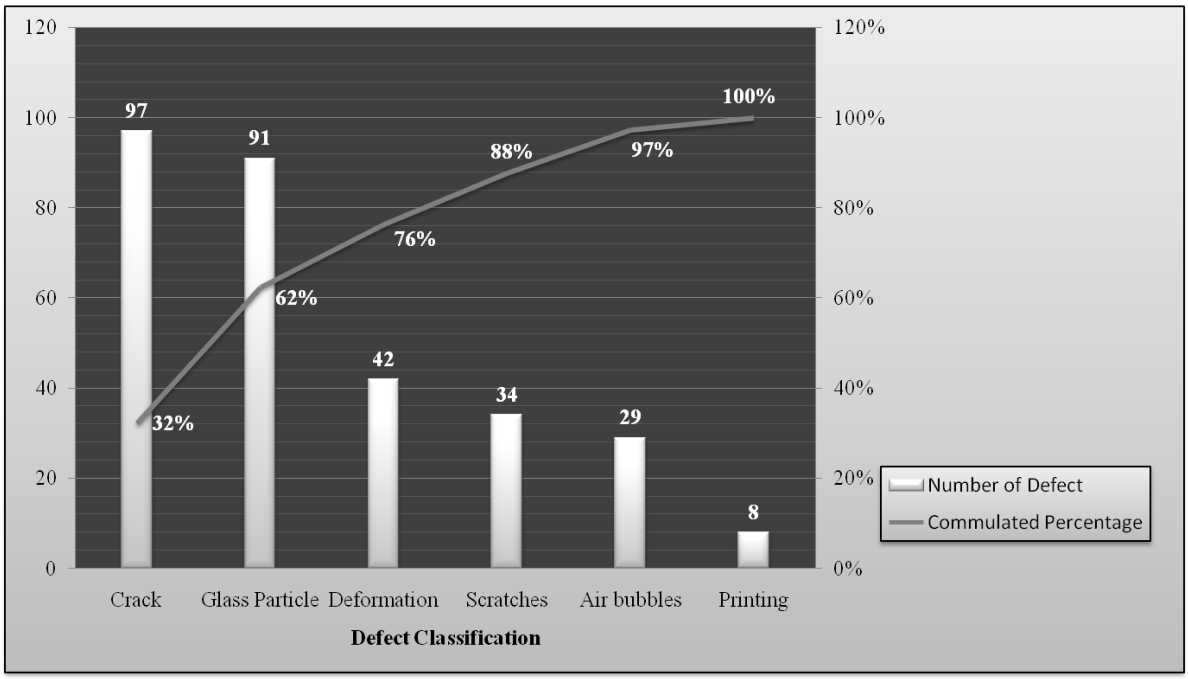


Figure 4.5 Pareto Diagram of Defect Occurence of Ampoules

Based on the data, crack problem is defect problem than can detect visually, perhaps during the shipment many ampoules are crack and it could be caused by annealing process is not right. There are several types of crack of ampoule; they are bottom crack, body crack, and neck crack.

4.2 Data Analysis

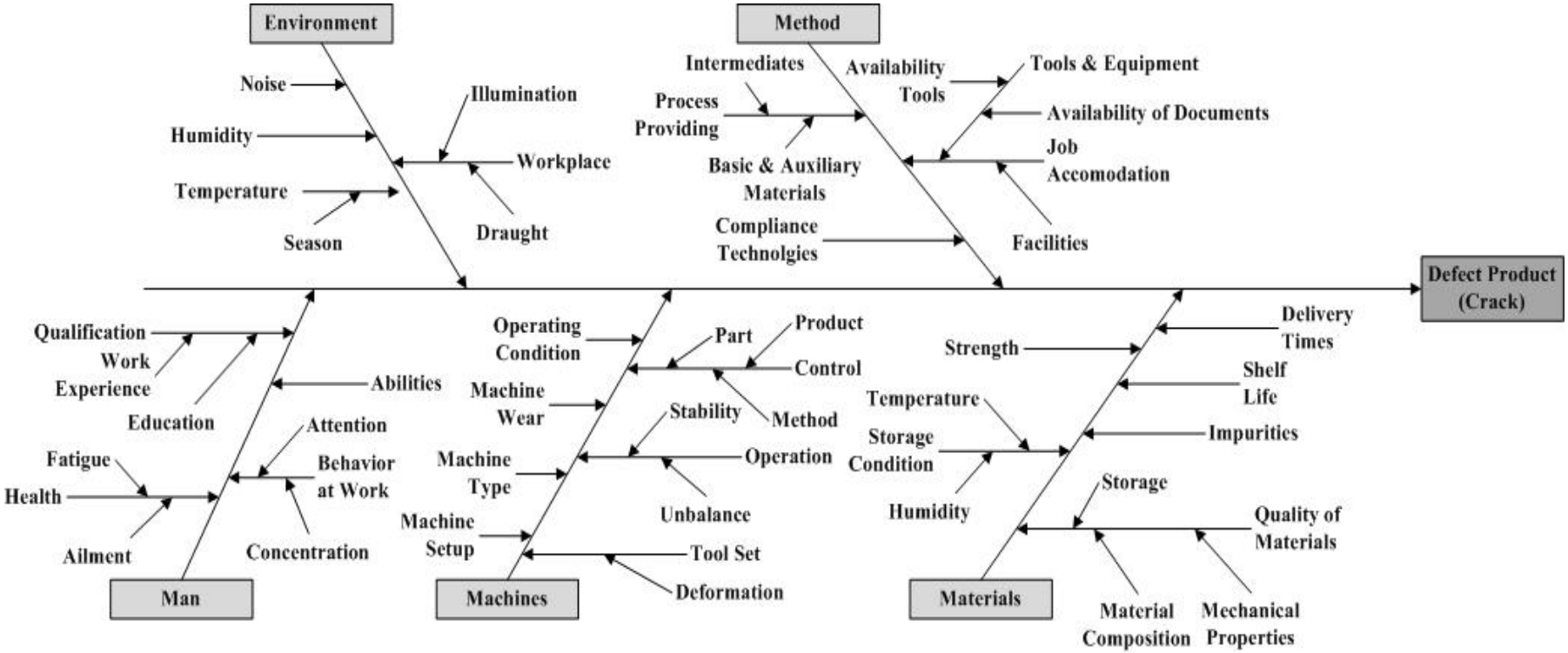


Figure 4.6 Cause and Effect Diagram of Crack Problem

As shown in figure above, the Fish bond graph show the possible main problem that created Defect product. In visual inspection before, the defect product already define which is Crack. The first possible main problem is based on material. In this case, the quality of material and storage condition will become the concern point to find the main problem of defect product. The qualities of materials are related to material properties, material composition, and the strength. Then, storage conditions are related to humidity, delivery time, impurities, temperatures, and shelf life.

The second possible main problem is based on the machine. In this category, there are several indicators that related to machine setup, machine type, machine wear, operation condition, controlling which concern with product, part and method, the next is operation which concern with stability and unbalance of machine, then the tool set indicator which concern with deformation.

The third possible main problem is based on the human resource or man power. In this category, there are several indicators that related to health of the operator which concern with fatigue and also ailment, qualification that concern with work experience, also education, then abilities and operator behavior that concern with attention of the operator itself during the operation time and also the concentration.

Then, the next possible main problem, it could be from the environment category. In this case, there are several indicators that related to noise of the working place, humidity, temperature which concern with season, and also workplace that concern with draught and illumination of workplace.

After classifying the possible main problem of defect product, the FMEA analysis will be conducted in order to know the quantitative judgments in founding the main problem. As we know FMEA is one of decision tool that already used by the company. This method allows us to determine the main problem in defect product as our main concern to improve for the next action.

Table 4.2 FMEA Analysis

Product/ Process	Failure Mode	Failure Effects	SEV	Causes	OCC	Controls	DET	RPN
Quality Inspection	Crack	Re-produce the product	7	Material	5	Find a new supplier	5	175
Quality Inspection	Crack	Re-produce the product	7	Material	5	Check raw material before use	2	70
Quality Inspection	Crack	Re-produce the product	7	Human Resources	3	Give the operator a training	5	105
Quality Inspection	Crack	Re-produce the product	7	Method	4	On line inspection and confirm the SOP	3	84
Quality Inspection	Crack	Re-produce the product	7	Machine	4	Check and control the machine once a week	5	140
Quality Inspection	Crack	Re-produce the product	7	Machine	7	Repair and maintain the machine	4	196
Quality Inspection	Crack	Re-produce the product	7	Machine	7	Change the old machine with the new one	6	294
Quality Inspection	Crack	Re-produce the product	7	Environment	4	Improve the workplace	4	112

In order to determine the main problem of defect product, the FMEA will be conducted. As known before, FMEA is a tool use to detect a part or a process with

failure risk in fulfilling a specific requirement, created with defect or different and those failure modes will result to the customer when the failure mode is not prevented or corrected. (Crow, 2002).

Then, in conducting the FMEA, there several rank that should be determine based on the table rank that shown in chapter two, which are the severity rating in table 2.1, occurrence rating in table 2.2, and detection rating in table 2.3.

After determined the rank, the indicator that already found in fish bond will be judge. Those indicators which are material, machine, man, method and environment that will be cause in FMEA table. For example, in the first problem which is caused by the material and it is have to be controlled by find a new supplier of material that has good quality than before.

The judgments is based on authorize person from the company. For instance, re-produce the product will have rating 7, the material 5, and the controlling which is found a new supplier will have rating is 5 (five). These judgments have to be calculated as RNP by multiplying severity, occurrence, and detection rating. The others causes have been judged and calculated as same as the first cause.

Finally, after judged and calculated the causes in FMEA table, the highest RPN will become the main problem of defect product, which is 294, belongs to machine cause.

CHAPTER V
CONCLUSION AND RECOMMENDATION

5.1 Conclusion

So, in this research, it is concluded that:

- The reoccurrence of the problems or failure which causing detected products in PT. SIG can be reduced and prevented by application of root cause analysis and FMEA by solving the problem itself.

- In Pareto Diagram, the biggest number of defect occurrence is crack problem; it has occurrence number 97 units during the January, 1th 2014 until July, 28th 2014 and the smallest number of defect occurrence is printing problem that only appear 8 units.

- The highest RPN will become the main problem of defect product, which is 294, belongs to machine cause.

5.2 Recommendation

Although the result of the study has reduce the defected product, it is still recommended to do the further study in order to keep improvement;

- Conducting a further study using the FMEA and Five Whys Analysis Method on the other failure modes; physical, quantity, package, and label problem in order to obtain better improvements.

- Conduct Analytic Hierarchy Process in Multi Attribute Failure Mode Analysis (MAFMA) method to eliminate the causes of defect product that can improve the product quality by adding the most important aspect which is internal failure cost.

- It is also recommended for PT. SIG to improve and increase the smallest amount of defects and nonconformity reductions which are caused by the

lack quality of material and human resources by finding a new supplier of the material also check the material before use, and increase the quality of human resources despite of giving them regular training but also strictly educated them in order to increase their personal awareness in the workplace.

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APPENDIX

Appendix 1. Table of Defect Data Products

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
Jan/10/2014	Printing	Quality Inspection	Missing OPC Dot	Machines
Jan/15/2013	Printing	Quality Inspection	Printing pell-off	Machines
Feb/11/2014	Printing	Quality Inspection	Missing OPC Dot	Machines
Feb/13/2014	Printing	Quality Inspection	Missing OPC Dot	Machines
Feb/20/2014	Printing	Quality Inspection	Missing ID Ring	Machines
Feb/21/2014	Printing	Quality Inspection	Missing ID Ring	Machines
Feb/26/2014	Printing	Quality Inspection	Missing Color Break	Machines
Mar/03/2014	Printing	Quality Inspection	Printing pell-off	Machines
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Human Resource
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Human Resource
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Environment
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Environment
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Methods
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Environment
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Environment
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Environment
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Environment
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Environment

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Raw material
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Environment
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm²	Human Resource
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Human Resource
	Air Bubbles	Quality Inspection	Diameter > 0.5 to 1mm	Raw material
	Air Bubbles	Quality Inspection	Diameter > 1mm	Raw material
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	More than 4 scratches	Raw material
	Scratches	Quality Inspection	1 radial scratch width > 0.2mm and over total circumference	Raw material
	Scratches	Quality Inspection	More than 4 scratches	Environment
	Scratches	Quality Inspection	More than 4 scratches	Human Resource
	Scratches	Quality Inspection	More than 4 scratches	Environment
	Scratches	Quality Inspection	More than 4 scratches	Raw material

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Scratches	Quality Inspection	More than 4 scratches	Environment
	Scratches	Quality Inspection	More than 4 scratches	Raw material
	Scratches	Quality Inspection	1 radial scratch width > 0.2mm and over total circumference	Human Resource
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Environment
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Human Resource
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Human Resource
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Raw material
	Scratches	Quality Inspection	2 or more scratches width > 0.2mm and > sum of length > 40mm	Human Resource

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Methods
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Methods
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Human Resource
	Scratches	Quality Inspection	1 scratch width > 0.2mm and length > 20mm,	Raw material
	Scratches	Quality Inspection	More than 4 scratches	Raw material
	Scratches	Quality Inspection	More than 4 scratches	Methods
	Scratches	Quality Inspection	More than 4 scratches	Human Resource
	Deformed	Quality Inspection	Deformed container function impaired	Raw material
	Deformed	Quality Inspection	Deformed container function impaired	Raw material
	Deformed	Quality Inspection	Deformed container function impaired	Raw material
	Deformed	Quality Inspection	Deformed container function impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Raw material
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Machines
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource
	Deformed	Quality Inspection	Deformed container function not impaired	Human Resource

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Machines
	Deformed	Quality Inspection	Deformed container function impaired	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Raw material
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Raw material
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Methods
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Raw material
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Methods
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Methods

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Raw material
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Methods
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Removable during washing > 0.2mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Methods
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Human Resource
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Raw material
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Glass Particle	Quality Inspection	Not removable during washing > 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Glass Particle	Quality Inspection	Not removable during washing > 0.2mm to 0.5mm	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Crack	Quality Inspection	Any size, penetrating the wall	Material
	Crack	Quality Inspection	Any size, penetrating the wall	Material
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Mathod
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Mathod

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Mathod
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Defect leading to leaks or breaks e.g. - crack, grooves, scars, chipped places.	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Mathod
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Human Resource
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Human Resource
	Crack	Quality Inspection	Defect do not lead to leaks or breaks	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines

Defect Confirmation Date	Defect Classification	Defect Detected	Description	Defect Causes
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Material
	Crack	Quality Inspection	Any size, penetrating the wall	Material
	Crack	Quality Inspection	Any size, penetrating the wall	Human Resource
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Machines
	Crack	Quality Inspection	Any size, penetrating the wall	Material