CHAPTER I
INTRODUCTION

This chapter contains the research background, problem formulation, research objectives, research scopes, and outline of the final project report.

1.1 Background

The global spending on medicines is increasing from year to year. It can be seen from Global Medicine Spending and Growth 2009-2023, as shown in **Figure 1.1**.

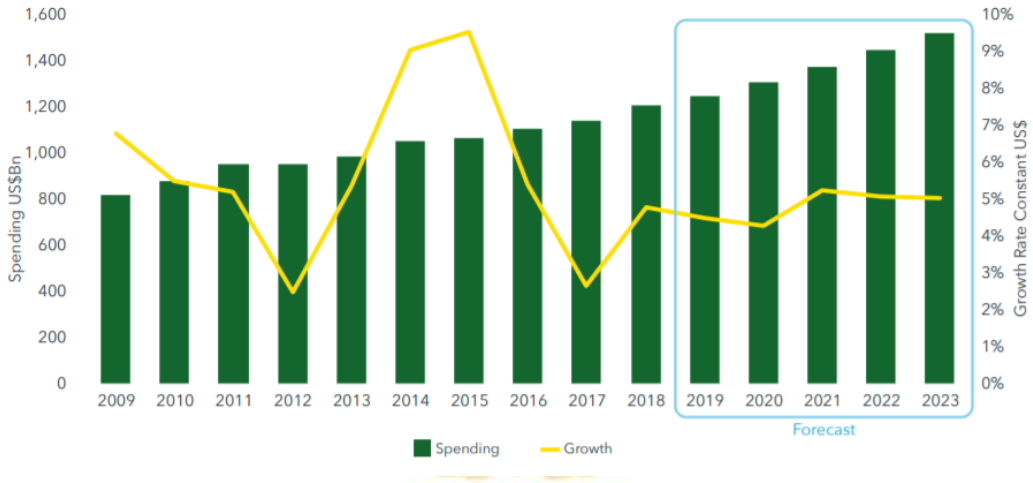

Figure 1.1 Global Medicine Spending and Growth 2009-2023 (IQVIA Institute, 2018)

The global pharmaceutical market will exceed $1.5 trillion by 2023, growing at a 3–6% compound annual growth rate over the next five years (IQVIA Institute, 2018). In Indonesia, the chemical, pharmaceutical, and traditional medicine industries grew by 8.48% in 2019. It can be seen from Analysis of Indonesia's Industrial Development, 1st Edition – 2020 as shown in **Figure 1.2**.

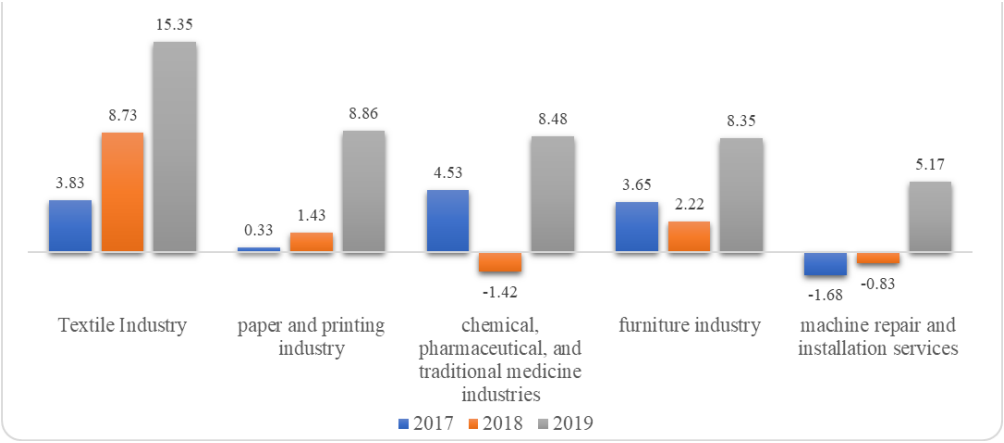

Figure 1.2 Analysis of Indonesia's Industrial Development, 1st Edition – 2020 (Ministry of Industry Republic of Indonesia, 2020)

Figure 1.2 shows that the pharmaceutical industry grew in 2019. This is resulting in the competition among the pharmaceutical companies become higher. The companies must have a competitive advantage to win the competition, one of the strategies is by fulfilling the customer needs, which provide the customer with good quality products.

PT. Nusantara Beta Farma is a pharmaceutical industry located in West Sumatra at Pasar Usang, Padang-Bukittinggi Roadway. PT. Nusantara Beta Farma produces medicines and cosmetics. Products manufactured by PT. Nusantara Beta Farma such as Obat Merah (Povidone Iodine), Obat Batuk Hitam (Cough Medicine), Beta Bethin Antiseptic Solution (Antiseptic), Beta Alcohol 70%, Chlorine, Borax Glycerin, and Salisil Talk Wangi (Perfumed Salicylic Talc).

PT. Nusantara Beta Farma, as a pharmaceutical company, has followed the standards set by the government. In Indonesia, every pharmaceutical company must implement Good Manufacturing Medicine Practices (GMMP) and Good Cosmetics Manufacturing Practices (GCMP) based on the Decree of the Minister of Health of the Republic of Indonesia No. 43 / MenKes / SK / II / 1988 and The Regulation of the Head of the Food and Drug Supervisory Agency Number HK.03.42.06.10.4556 of 2010.

One of the criteria for a product is defective if it does not meet the etiquette standards of PT Nusantara Beta Farma. The standard refers to GMMP and GCMP at PT Nusantara Beta Farma. The weight allowed by the company is 287 ± 287 x 5% grams. The value of 287 grams is the weight of 1 series of Perfumed Salicylic Talc products. So that the product weight allowed for the Perfumed Salicylic Talc product range is 273 grams - 301 grams, if the Perfumed Salicylic Talc product is outside the specified weight limit, the six sachets product will be refilled so that no serial product is out of control. Measurement of the weight value is carried out during Perfumed Salicylic Talc's production process for all available colors. This process is called In Process Control (IPC) which is done every 15 minutes during the production process. This is done to reduce the number of products outside the weight limit allowed.

PT. Nusantara Beta Farma sets 5% as the maximum proportion of defective products per day. Based on the results of interviews with the representative of the quality control division, it was found that the product that has many problems in its quality is Perfumed Salicylic Talc. Meanwhile, other products found few problems and did not require special handling.

Any defective products will cause additional costs and losses for the company. Also, defective products can harm consumers who use Perfumed Salicylic Talc products, thus causing Perfumed Salicylic Talc products not to sell in the market.

Perfumed Salicylic Talc product has four perfume variants, divided by color, which are red, blue, yellow, and green. Every day the company only produces a maximum of 2 types of perfume variants. Products with different colors will be produced after the first color product has been produced. This is done to avoid mixing the ingredients in each color in the Perfumed Salicylic Talc product.

The number of Perfumed Salicylic Talc products produced by PT Nusantara Betafarma varies every day. The amount of Perfumed Salicylic Talc produced

depends on market demand and differs for each type of perfume. PT Nusantara Beta Farma always maintains its powder quality. Before the powder is packaged, the quality staff will check the powder quality and ensure that it conforms to company standards. So, there is no problem with the powder content, and the failure can only happen in the packaging process.

Perfumed Salicylic Talc products manufactured at PT Nusantara Beta Farma produce several defective products that do not comply with the company's standards. There are three types of defects in Perfumed Salicylic Talc. The first is a leak, this type of defect when there is a hole or a path through which the package contents may escape or through which ambient materials from the environment may enter. The second is the unclear batch number, this type of error if the batch number difficult to read. The third is no thread. If there is no thread in the package, that makes the package bubble.

The number of defective products from Perfumed Salicylic Talc products varies every day. The most common type of damage is a leak. The percentage of leak type damage reached 91,58% of the total defect items of 14.316 sachets for all types of Perfumed Salicylic Talc. The total damage several times exceeded the company's standard limit so that it could cause losses to the company. So, handling is needed to reduce the number of defects per day so that the company does not experience losses in production.

Many industries implement the six-sigma concept to maintain their quality. Today, Six Sigma is one of the primary quality initiatives that have been billed as a critical business tool in the 21st century (Pepper and Spedding, 2010; Mader, 2008). Six Sigma helps industries improve organizational efficiencies and customer satisfaction and reduces operating costs, and increases profits (Laureani et al., 2013). Six Sigma's unique approach to continuous process and quality improvement is DMAIC methodology. DMAIC is an acronym from the words Define-Measure-Analyze-Improve-Control. This method is based on process improvement according to the Deming cycle. It is a process improvement of many different areas

in the enterprise. DMAIC cycle consists of five stages which are connected to each other (Sokovic et al., 2010; Sin et al., 2015)

Therefore, the method or approach DMAIC (Define, Measure, Analyze, and Improve) will be used to improve the quality of a product in this research. This method is used because it can eliminate defects and improve the quality of the observed process. At the measuring stage, the P control map is used because the data used in this study are attribute data. Meanwhile, the analysis stage is carried out using the Fishbone diagram and Failure Mode and Effect Analysis. The final output expected from this research is the provision of recommendations for the improvement of the quality of the production process on the Perfumed Salicylic Talc product. It is expected that later the cost of losses suffered by the company will be small by reducing the number of defective products that occur in Perfumed Salicylic Talc products.

1.2 Problem Formulation

Based on the data obtained when conducting the preliminary survey, it is known that there is data on the proportion of defects per day that exceed the limit set by the company. The limit set by the company per day is 5%. Meanwhile, Perfumed Salicylic Talc products were found a defect proportion that exceeds the stipulated limit. So, this causes the company that needs to rework the product to fix the quality. The company's rework process can increase production costs and require more time than usual. So, the formulation of the problem in this study is how to minimize the number of defective products of Perfumed Salicylic Talc in PT Nusantara Beta Farma using the DMAIC method.

1.3 Research Objective

The purpose of this research is as follows:

1. To identify the causes of the defective product of Perfumed Salicylic Talc
2. To provide some improvement on Perfumed Salicylic Talc Production

1.4 Research Scope

The scope of this research are as follows:

1. The product studied in this study was the yellow Perfumed Salicylic Talc Sachet.
2. This study is only focused on the quality packaging of Perfumed Salicylic Talc.

1.5 Outline of Final Project Report

This part contains the systematic writing of the final project report, which are as follows:

CHAPTER I INTRODUCTION

This chapter explains the background of the research, the problem formulation, the objectives of the research, the scope of the study, and the outline of the final project report.

CHAPTER II LITERATURE REVIEW

This chapter contains the theories used in this study, such as quality, quality control, statistical quality control, seven basic quality tools, Six Sigma DMAIC (Define Measure Analysis Improve Control), and Failure Mode and Effect Analysis (FMEA).

CHAPTER III RESEARCH METHODOLOGY

This chapter contains the procedures and methods used in conducting research.

CHAPTER IV RESULT AND DISCUSSION

This chapter contains an evaluation of the Perfumed Salicylic Talc production process that occurs at PT Nusantara Betafarma. This evaluation stage consists of define, measure, analyze, and improve (proposed improvements) for product quality that is not in accordance with specifications.

CHAPTER V CONCLUSIONS AND SUGGESTIONS

This chapter contains the conclusions of the research and the suggestions for further study.