CHAPTER I
INTRODUCTION

Chapter I consists of the background problems, problem formulation, research objectives, research scope, and outline of the report.

1.1 Background

Gambier is an extract of the sap of leaves and twigs from the dried gambier plant (*Uncaria Gambier Roxb.*) (Anungputri, 2010). This commodities can be used for betel food, raw materials for the pharmaceutical industry, food, textile industries, raw materials in the cosmetic industry as antioxidants and anti-bacteria, and raw materials dyes that are resistant to sunlight. With its main components, catechins and tannins, Gambier includes complex compounds from the polyphenol group with a flavonoid structure with antioxidant activity (Muchtar et al., 2010).

Indonesia is the largest gambier exporting country globally to be dominated by India, Japan, Pakistan, the Philippines, Bangladesh, Malaysia, and several countries in Europe (Kontan.co.id, 2019). According to DetikFinance (2019), the Director-General of Plantation of the Ministry of Agriculture (Kementan) Kasdi Subagyono said that 80% of the world's gambier production and export market comes from Indonesia. According to data from the Directorate General of Plantations, Ministry of Agriculture, in 2018, Indonesian gambier's export value reached 18,000 tons or USD 55 million (Ditjenbun, 2019). Most of the national gambier needs are supplied by West Sumatra, which is 80%, with details of 70% coming from Limapuluh Kota Regency and 30% from Pesisir Selatan Regency (Public Info, 2020).

Even so, the volume and value of Indonesian gambier exports are still fluctuating (Hosen, 2017). One of the causes of this condition is the unstable productivity of Indonesian gambier. This can be seen in **Figure 1.1** below, which

presents productivity data for West Sumatra's gambier as one of the suppliers of Indonesia's gambier needs.

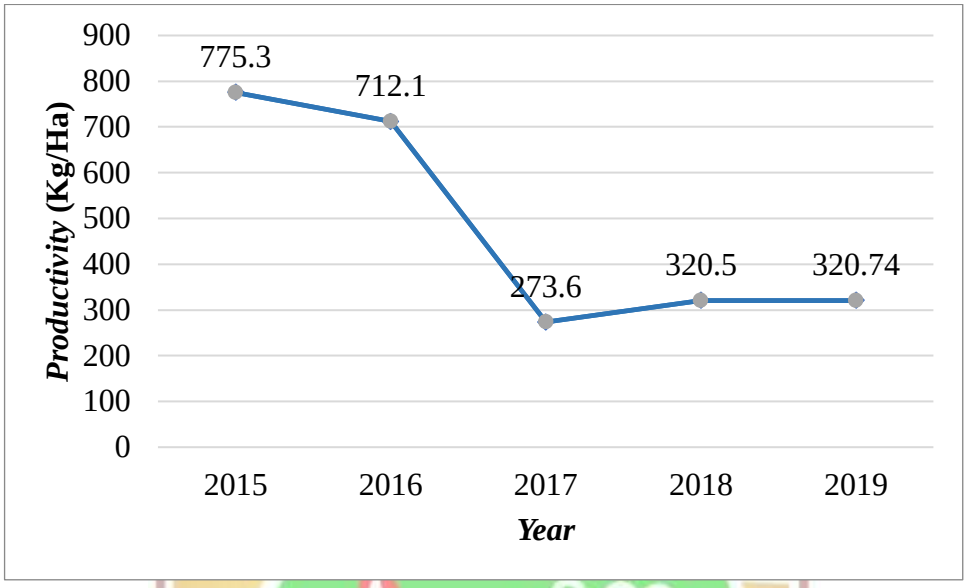

Figure 1. 1 West Sumatra Gambier Productivity 2015-2019
(Source: BPS Sumatra Barat, compiled by the author)

Apart from the stable production condition, another cause of the problem in gambier production is product quality (Dhalimi, 2006). So far, the quality of Gambier has been determined by farmers and traders without any written standards. Farmers and traders have traditionally defined the quality by looking at the colour, shape of the cup (mold), and weight, regardless of moisture content, ash content, and so on (Amos et al., 2004). As a result, gambier products exported by Indonesia are valued at low value by the world market (Yudha, 2017). Through the National Standardization Agency (BSN), the Indonesian government has determined the quality of tradable gambier based on SNI 01-3391-2000.

One of the currently developed unit to produce and market gambier derivative products is Teaching Industry Gambier Andalas University (TIG Unand). The teaching industry's basic concept is the transfer of a part of the educational process and industrial processes in a learning design, so that competency-based education can be provided, creating human resources ready to face global competition (STTN Batan, 2020). Teaching Industry builds business

units in universities to learn for students and introduce innovative products in Higher Education (Hawati et al., 2019). Based on the Terms of Reference for the Performance of the Directorate General of Innovation Kemristekdikti 2018 in Hawati et al. (2019), Teaching Industry is industry-oriented learning, which is learning carried out by higher education through collaboration with industry or the business world that integrates the educational curriculum with the needs and dynamics of technological development.

Teaching Industry Gambier Andalas University is located in the northern Andalas University area, precisely between the Andalas University Futsal Field and the Medicinal Plant Garden. The location of TIG Unand can be seen in **Figure 1.2**. TIG Unand was founded in mid-2019 and is under the auspices of the Science Techno Park (STP) of Andalas University. TIG Unand is developing and transferring production technology for raw materials and downstream products originating from gambier. The main activity of TIG Unand is to produce derivative products of gambier such as catechins with levels of 90% and to produce tea derived from gambier leaves. However, since it was founded and inaugurated in September 2020, TIG Unand has not yet carried out its first production process (Universitas Andalas, 2020).

Figure 1. 2 Location of the TIG Unand
(Source: Google Maps)

The product of TIG Unand consist of Catechins and Gambier Tea. Catechins are flavonoid compounds that are antioxidants. Catechins are used as active ingredients for drugs and cosmetics, also additive substance for foods, beverages, and chemical products (Kurniatri et al., 2015). The number of catechins needed in producing several products based on data in 2009 can be seen in **Table 1.1** below. Whereas, Gambier tea is a product produced from the processing of gambier leaves. Gambier leaves contain complex polyphenols, so that they are very potential for antioxidants (Aditya & Ariyanti, 2016). Several researchs have shown that antioxidants are very good for the human body. The function of antioxidants to protect cells from free radical damage (Alodokter, 2020)

Table 1. 1 The Potential Demand of Catechins for Export Products

No.	Potential Products of Catechin Users	Export (Kg)	Percent of Catechins Required in Material (%)	The volume of Catechins Needed (kg)
1.	Toothpaste	2,178,636	0.2	4,357.27
2.	Mouthwash etc.	72,180	0.2	144.36
3.	Outer shell preparations	2,704,556	1	27,045.56
4.	Anti acne cream	9,253	1	92.53
5.	Cosmetics for treating damaged hair	725,110	0.1	3,626.56
6.	Compact powder or powder	1,638,193	0.3	44,914.58
7.	Face & skin cream & lotion	8,413,680	1	84,136.80
8.	Bath soap	153,626,110	0.01	15,362.61
9.	Other external skin care	7,253,110	12.77	926,222.15
10.	Cancer drugs	47,761	10	4,776.10
11.	Drink	1,877,885	1	3,755.77
Total				1,089,457.36

Source: LPPM Universitas Andalas (2019)

As a unit that will produce and market gambier derivative products, TIG Unand certainly has to ensure that the products it produces are good quality and safe. Quality and safety products are free from bacteria and not contaminated from raw materials until finished products. One of the tools used to maintain product safety is Hazard Analysis Critical Control Points (HACCP) (Ilmiawan et al., 2018).

HACCP is a tool used to assess the level of danger, estimate risk, and determine the appropriate measure in supervision, with an emphasis on prevention and process control rather than final product testing, which is usually carried out in a traditional surveillance manner (Suklan, 1998). The HACCP approach will help plan various food safety and health education activities that focus on the various hazards associated with the types of food consumed and food processed and prepared (Sudarmaji, 2005).

For the HACCP system to function appropriately and effectively, it is necessary to fulfil the basic requirements program (pre-requisite). A pre-requisite is a general procedure related to a food business operation's basic requirements to prevent contamination due to food production or handling operation (Susiwi, 2009). The basic requirements for HACCP implementation are the implementation of

Good Manufacturing Practices (GMP) and Sanitation Standard Operating Procedures (SSOP) (Barros-Velazquez, 2016).

Good Manufacturing Practices (GMP) is an essential requirement that should be met by a company that wants to consistently produce quality and safe food (Bimantara & Triastuti, 2018). Good Manufacturing Practices (GMP) requirements include requirements for production, location, buildings and facilities, production equipment, and employees (WHO, 2015). The virtue of implementing GMP is to prevent contamination of the product during the production process. The product that reaches the consumer is a product that is safe for consumption. The broad application of GMP will have implications for many aspects related to the hygiene of company employees and the sanitation of the production process (Agustin, 2020).

GMP is implemented during the initial production process (receiving raw materials) to the storage of finished products (Latief & Trimo, 2019). Based on the website Drs. J. Tanzil and Associates, all industries related to food, medicine, cosmetics, and animal feed are required to implement GMP since the factory was established, and the first process was carried out. In general, the application of GMP can refer to various references because so far there is no set international standard like the ISO standard. In Indonesia, GMP standards are issued by the BPOM (Indonesian National Agency of Drug and Food Control) according to the type of product produced (Al Hasan et al., 2019). In the food industry, guidelines for Good Manufacturing Practices for Food Production (Cara Produksi Pangan Olahan yang Baik/CPPOB) are stipulated through the regulation of the Minister of Industry of the Republic of Indonesia number 75 / M-IND / PER / 7/2010. In the pharmaceutical industry, one of which is a guideline on Good Manufacturing Practices for Active Pharmaceutical Ingredients (Cara Pembuatan Bahan Baku Aktif Obat yang Baik/CPBAOB). In the rest of this report, these guidelines are called CPPOB and CPBAOB.

Other pre-requisite programs that must be applied to companies to maintain product safety are SSOP or Sanitation Standard Operating Procedures. According to Corlet (1998) in (Efendi, 2007), Sanitation Standard Operating Procedures is a written procedure that food processors must use to meet sanitation conditions and food factories' practices. A good sanitation program will control many biological, chemical, and physical hazards in a food operation.

In addition, the application of GMP and SSOP is one of the requirements in product certification required by the Indonesian National Agency of Drug and Food Control (BPOM), so that business actors can obtain product distribution permits (BPOM RI, 2017). These requirements are contained in BPOM regulation number 27 of 2017 concerning Processed Food Registration. TIG Unand requires a marketing permit issued by BPOM RI or an authorized institution as a unit that will market products. To fulfill this, TIG Andalas University must meet the requirements for implementing GMP and SSOP.

The thing that must be considered in implementing the pre-requisite is the program must be documented. The documentation of the program is evidenced by the existence of Standar Operating Procedure (SOP), Work Instruction, and recording forms that establish standards and production process instructions. Based on the results of a visit to TIG Unand, it was found that the Teaching Industry did not have a document that explained the standards for implementing the pre-requisite program, namely GMP and SSOP. Based on that problem, this research was conducted to identify and design the documents to implement GMP and SSOP. The document consist of Standar Operating Procedure (SOP), Work Instruction, and recording forms. The documented application of GMP and SSOP will help the Teaching Industry Gambier implement a food safety system in the production process. The products produced will be of high quality and safety and obtain a distribution permit from BPOM RI.

1.2 Problem Formulation

The formulation of the problem in this research is how to design standard documents to implement Good Manufacturing Practices (GMP) and Sanitation Standard Operating Procedures (SSOP) in TIG Unand, following the requirements set by the Indonesian National Agency of Drug and Food Control (BPOM)?

1.3 Research Objectives

The objectives of this study is to design a standard document consisting of SOP, work instructions, and recording forms on the production process of cathechins and gambier tea at TIG Unand. The document will be design based on the principles of Good Manufacturing Practices (GMP) and Sanitation Standard Operating Procedures (SSOP).

1.4 Research Scopes

The research scopes in this study are as follows:

1. The design of GMP documents based on regulations or guidelines stipulated by the Indonesian National Agency of Drug and Food Control (BPOM) in the Food Industry, i.e. Good Manufacturing Practices for Food Production (CPPOB), and in the drug industry, i.e. Good Manufacturing Practices for Active Pharmaceutical Ingredients (CPBAOB).
2. The design of GMP and SSOP documents was carried out based on the activities of TIG Unand.
3. The designed documents are still in the form of draft proposals and have not been implemented yet.
4. The designed documents are not considered the Hazard Analysis Critical Control Point (HACCP) because the production have not started yet.

1.5 Outline of Final Project Report

The outline of this final project report are as follows:

CHAPTER I INTRODUCTION

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

CHAPTER II LITERATURE REVIEW

This chapter contains the theoretical basis of several literature pieces that are used as a reference in solving problems in this study. The theory used consists of Good Manufacturing Practices (GMP), Good Manufacturing Practices for Food Production (CPPOB), Good Manufacturing Practices for Active Pharmaceutical Ingredients (CPBAOB), Sanitation Standard Operating Procedure (SSOP), SOP, work instructions, recording form, and previous research.

CHAPTER III RESEARCH METHODOLOGY

This chapter contains the stages of research methodology. The research stages began with field observations and conducting interviews with related parties. These stages are described in description form and depicted in the form of a flow chart.

CHAPTER IV DESIGN OF GMP AND SSOP DOCUMENTS

This chapter contains a review of the readiness for the implementation of GMP and SSOP as well as the design of documentc consisting of SOPs, Work Instruction, and Record Forms. Document design is carried out through the stages of identifying the structure and production process, details of activities, RACI Matrix, and document preparation.

CHAPTER V CONCLUSIONS

This chapter contains conclusions and suggestion from the results of research that has been carried out. Suggestion are given as consideration for further research.