

CHAPTER I

INTRODUCTION

1.1 Research

Habbatussauda' Or black cumin is a plant that has been known for thousands of years and is widely used by Middle Eastern people to treat various diseases. Compounds in it such as *thymoquinone*, *nigellone* and so on in *habbatussauda'* are believed to boost immunity. Empirically *habbatussauda'* has been used as a traditional remedy to improve immune response and boost stamina¹. Modern experiments on humans and animals prove that *habbatussauda'* has an antimicrobial effect, regulates blood pressure and use other terms asthma. *Habbatussauda'* has a small and partial composition, but it has an important value in medicine. Such as improve the function of the body's organs, overcoming diseases and effects on the sources of disease².

Muslims believe that *habbatussauda'* can be a cure for all diseases except old age and death. This refers to the hadith of the Prophet Muhammad SAW:

قَالَ رَسُولُ اللَّهِ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ: عَلَيْكُمْ بِهَذِهِ الْحَبَّةِ السَّوْدَاءِ، فَإِنَّ فِيهَا شِفَاءً مِنْ كُلِّ دَاءٍ إِلَّا السَّامَ. [رواه البخاري ومسلم]

"The Messenger of Allah (peace and blessings of Allaah be upon him) said: "Indeed, in *habbatussauda'* (black cumin) there is a cure for all kinds of diseases except as-saam, and as-saam is death, and *habbatussauda'* (*Nigella sativa*) is Asysyuniz." (HR. Bukhari and Muslim)³

Habbatussauda' is often applied in capsules containing powder or oil. However, using it in this way is considered less effective because it often leaves a feeling of discomfort in the throat. So it is necessary to develop innovations. One of the innovations is in lozenges dosage form. Lozenges solid preparations that contain one or more substances that are efficacious and have a sweet taste. The

¹ Tanti Dwi Gunawati, Febrina Mahmudah, and Yurika Sastyarina, "Studi Literatur: Aktivitas Imunomodulator Tanaman Jintan Hitam (*Nigella sativa* L.)," *Proceeding of Mulawarman Pharmaceuticals Conferences* 12 (December 16, 2020): 211–17

² Alfandi Ilham Safarsyah, "Hadits Nabi Saw Tentang Obat Dalam Tinjauan Ilmu Kedokteran Modern" 12, no. 2 (2018).

³ Safarsyah.

sweet base is meant to dissolve or disintegrate slowly in the mouth and has a good taste⁴.

The advantages of lozenges include a good taste and are more accepted by pediatric and geriatric patients, increasing the retention time of drugs in the oral cavity, reducing gastric irritation, and being easy to store and to use them⁵. The advantage of lozenges over other pharmaceutical preparations is that the accuracy in dosage is relatively stable and safer than parenteral preparations⁶. Some of the methods that can be used in the manufacture of lozenges are wet granulation, dry granulation and direct felting. In this study, the wet granulation method was used.

According to Suciati (2019)⁷, the manufacture of lozenges of *Habbatussauda*' extract by combining crushing and binding materials will affect the physical properties of the granules and lozenges. Where the method used in making the granules is the wet granulation method with 70% ethanol spraying⁸. The wet granulation method is used to improve the flowability and produce tablets that are not easily broken. The advantages of this method are that it increases the adhesive strength and compaction ability of the powder, as well as prevents the separation of the mixed components during the manufacturing process⁹.

Habbatussauda', also known as black cumin, has a variety of health benefits that have been widely known, such as anti-inflammatory, antibacterial, and increasing immunity. However, to make it an effective and safe drug, it is necessary to conduct research on the characteristics of the lozenges preparation, which includes physical testing as well as ensuring that *the extract* can be released appropriately through a wet granulation process. The wet granulation method was

⁴ Renuka Pothu and Madhusudan Rao Yamsani, "Lozenges Formulation And Evaluation: A Review" 5, no. 5 (n.d.).

⁵ Minakshi Rathod et al., "Medicated Lozenges As An Easy To Use Dosage Form," *World Journal of Pharmaceutical Research* 7, no. 16 (n.d.).

⁶ Anugerah Suciati, Andi Sri Suriati Amal, and Lija Oktya Artanti, "Pengaruh Perbedaan Bahan Pengikat Yang Dikombinasikan Dengan Bahan Penghancur Dalam Sediaan Tablet Hisap Ekstrak Habbatus Sauda' (*Nigella sativa* L.)," *Pharmaceutical Journal of Islamic Pharmacy* 3, no. 2 (September 24, 2019), <https://doi.org/10.21111/pharmasipha.v3i2.3381>.

⁷ Suciati, Amal, and Artanti.

⁸ Suciati, Amal, and Artanti.

⁹ Oktavia Eka Puspita et al., "Studi Pengaruh Jenis Bahan Pengikat Sediaan Tablet Dispersi Solid Kunyit Terhadap Profil Disolusi Ekstrak Kunyit (*Curcuma domestica*)," *Pharmaceutical Journal of Indonesia* 8, no. 1 (December 30, 2022): 95–102.

chosen because it can help produce homogeneous granules and tablets with characteristics accepted for practical use¹⁰.

Thus, this research is very important to ensure that lozenges not only have optimal efficacy, but also safe, stable, and easy to use by consumers. In addition, the results of this study can be the basic knowledge for the development of more standardized herbal products, which can be relied in health therapy.

1.2 Research Problem

The formulation of the problem in this study are:

1. How are the characteristics of *Habbatussauda*' *extract lozenges* (*Nigella sativa*) that made by wet granulation method?
2. Which is the best formulation of *Habbatussauda*' *extract lozenges* (*Nigella sativa*) that made by wet granulation method?

1.3 Research Objectives

The objectives of this study are:

- 1 Determining the characteristics of *Habbatussauda*' *extract lozenges* (*Nigella sativa*) that made by wet granulation method
- 2 Knowing the best formulation of *Habbatussauda*' *extract lozenges* (*Nigella sativa*) that made by wet granulation method

1.4 Research Benefits

1.4.1 Theoretical Benefits

The results of this study can add to knowledge and be used as a reference material for further research on the use of active substances from *Habbatussauda* in the form of tablet preparations, especially lozenges.

1.4.2 Practical Benefits

The results of this study are expected to add to the treasure of science and increase readers' insights, especially for the use of active substances of *Habbatussauda* in the form of lozenges preparations.

¹⁰ Eka Puspita et al.

1.5 Authenticity of Research

Table 1. Authenticity of Research

Title	Research Methods	Variable	Result	Research Differences
Effect of different binding agents combined with crushing agents in the preparation of lozenges of <i>black pepper extract sauda' (Nigella sativa l.)</i> ¹¹	Laboratory experiments	Dependent: Hardness and fragility of the tablet Independent: Concentration of amylum Manihot and PVP as a binder and concentration of Avicel pH 102 as a crushing agent	The third formulation of <i>Habbatussauda'</i> extract lozenges with a combination of amylum Manihot and PVP as a binding agent and avicel PH 102 as a crushing agent showed the best physical properties of the tested tablets	Dependent: Evaluation of the quality of <i>Habbatussauda'</i> extract lozenges' Independent: concentration of <i>Habbatussauda'</i> extract'
Formulation of dry extract lozenges of <i>black pepper sauda' (Nigella sativa l.)</i> with a combination of sucrose-mannitol as a filler ¹²	Laboratory experiments	Dependent: Formulation of suction tablet preparations -I with sucrose-mannitol combination as filler Independent: Dried extract of <i>black pepper'</i>	Lozenges of dried extract of black pepper (1) with sucrose concentration (1): mannitol (5) have criteria for meeting the evaluation requirements of tablets as lozenges with tablet hardness of 8.57/kg, dissolution time of 13.27/min and fragility of 0.12%	Dependent: Evaluation of the quality of <i>Habbatussauda'</i> extract lozenges' Independent: concentration of <i>Habbatussauda'</i> extract'
Antioxidant activity test of ethanol extract and water extract of <i>Habbatussauda' (Nigella sativa)</i> ¹³	Laboratory experiments	Dependent: Antioxidant Activity Test Independent: Ethanol extract and water extract of <i>Habbatussauda's</i> seeds'	extracts by maceration method with ethanol solvents have an IC50 value of 4.402 while extracts evaporated by freeze dry have an IC50 value of 4.277	Dependent: Characteristics Test of lozenges by wet granulation method Independent: Concentration of <i>Habbatussauda'</i> extract'

¹¹ Suciati, Amal, and Artanti, "Pengaruh Perbedaan Bahan Pengikat Yang Dikombinasikan Dengan Bahan Penghancur Dalam Sediaan Tablet Hisap Ekstrak Habbatus Sauda' (Nigella sativa L.)."

¹² Yulisa Raras Dewi, "Formulasi Sediaan Tablet Hisap Ekstrak Kering Habbatus Sauda' (Nigella sativa l.) dengan Kombinasi Sukrosa-Manitol sebagai Bahan Pengisi," *Pharmasipha* 3, No. 1 (March 2019).

¹³ Yulian Catur Rini, Fitria Susilowati, and Andi Sri Suriati Amal, "Uji Aktivitas Antioksidan Ekstrak Etanol dan Ekstrak Air Biji Habbatussauda' (Nigella sativa)," *Pharmaceutical Journal of Islamic Pharmacy* 4, no. 1 (March 31, 2020), <https://doi.org/10.21111/pharmasipha.v4i1.3945>.