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Synthesis and Characterization of Capsule Shell Formulation Using *Konjac Glucomannan* as an Alternative Halal Binder

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Abstract

Background: In accordance with cultural and religious restrictions, certain consumers, notably among Muslims, Hindus, Jews, and vegetarians around the world, are concerned when gelatin used in capsules is produced from animal sources, particularly porcine and bovine. Therefore, an effort to develop halal, plant-based pharmaceutical ingredients and excipients has been made to solve this issue. Less studies have been conducted on *Konjac Glucomannan* in capsule production. Objective: This research was conducted by developing alternative plant-based capsule through dipping method and find the best formula that can achieve and fulfill good properties of capsules according to standards. Methods: Hard capsule shells were made using formulations such as konjac powder, sorbitol, starch, lactose and distilled water using dipping method. The best formulation of capsules was selected and then they were tested using weight variation test, swelling degree test, water content analysis, disintegration test and dissolution test to evaluate their physicochemical properties. Results: Based on the results of the study, antimicrobial of synthetic konjac powder is very minimal and to get optimum results of antimicrobial, extraction of *Konjac Glucomannan* from its plant is needed. There were nine formulations produced, however only three of the formulations were chosen which were formulation F7, F8 and F9. Formulation F8 was selected as the best formulation as its characterization results fulfils the standard requirement. Conclusion: In a nutshell, the usage of *Konjac Glucomannan* as an alternative binder is appropriate in production of capsules with addition of other polymers such as starch and lactose.

Keywords: *Konjac Glucomannan*, capsule, alternative, halal binder

Introduction

Excellent drug delivery system is a key component to a well-established production of medications in the pharmaceutical industry. In addition to the active pharmaceutical ingredients (API) in a drug, many dosage forms created today contain numerous extra components which referred to as excipients. Because they make up most of the formulation, it is always important to choose an excipient that satisfies the ideal properties for that product (Chaudari *et al*., 2012). To satisfy a good delivery system that would cater to different patients with various conditions, there would be many types of dosage forms according to the route of drug administration. Some of the extensively used dosage forms nowadays are tablets, capsules, and syrups. In this study, the focus would be on the capsules, which have taken a tremendous step forward in the development of new drugs. Capsules can be

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classified into two types which is hard-shell capsules and soft-shell capsules. These shells are mostly known to use gelatin as part of the production, and it is mostly considered non-halal in food and pharmaceutical products due to its source such as pig bones. The Muslim population is not allowed to consume any goods that contain pig derivatives, such as porcine gelatin.

The Arabic word "halal" refers to any goods that Muslims may consume in accordance with Syariah Law, the system of Islamic law (Sudjadi *et al*., 2015). The Global Halal Pharmaceutical Market 2017 states that Halal medicines are those that come from Halal sources and not containing any banned elements like alcohol or non-Halal animal products like pig or porcine products, as well as any other compounds that are prohibited by Islamic law. Other than porcine gelatin, it is also an issue for consumption of bovine gelatin. This is due tosome cases of bovine spongiform encephalopathy are linked to bovine gelatine that contains prion proteins which would cause consumers at risk. Thus, there is increased interest in the manufacture of alternative capsules derived from plants and marine sources due to the rejection of bovine and porcine based gelatin by some religions, including Muslims, Hindus, and Jews.Therefore, to advance the pharmaceutical sector by offering a variety of gelatin alternatives, this study will be centred on the synthesis of plant-based capsules employing *Konjac Glucomannan* using dipping method.

Materials and Methods

Antimicrobial Activity Test

Kirby-Bauer Disk Diffusion method was used to observe the antimicrobial activities of *Konjac Glucomannan*. This method allows identification of antimicrobial activities of *Konjac Glucomannan* using different concentrations by observing zone of inhibition. Three different concentrations of *Konjac Glucomannan* solution were prepared by diluting konjac powder with distilled water. Blank disk was immersed in the solution and dried. Both microbes were smeared on two different agar plates using streaking methods. Disk was then placed on the agar that was smeared with microbes using a sterile forceps. Along with the konjac-infused disk, gentamicin antimicrobial disk (positive control), disk that was immersed in distilled water and blank disk are also placed on the agar as comparison.

Preparation of *Konjac Glucomannan* Solution

Formulations were adapted from Mufrodi *et al*., (2019) and modifications were made. *Konjac Glucomannan* powder, sorbitol, and other variable ingredients (starch, lactose, microcrystalline cellulose etc.) were weighed with various amount. Distilled water was heated until it reached temperature of 60°C. Other ingredients other than sorbitol were added to the distilled water and stirred for 3 minutes. Sorbitol was added to the solution during stirring and the solution was continuously stirred for 15 minutes. Next, the solution was placed in water bath for 60 minutes which has been regulated to 80-90°C.

Formulation of Hard-Shell Capsules

Formulation of hard capsules were done through dipping method. As a substitute for capsule mold pins, stainless steel chopsticks ends were used to dip into the solution of konjac which has been prepared in previous steps. The mixture will then adhere to the chopsticks and began to harden. The solution on the chopsticks will be air dried for 30 to 60 minutes before it would be placed in an oven at 40°C for overnight.After drying in oven, formed capsule shells will be removed from the chopsticks and placed in petri dish. Most of the formulations require more time before it can be easily removed as capsule shells from the mold. In the case where the capsule is still slightly moist after being removed, it will be placed in the oven again for a few hours.

Characterization of Hard-Shell Capsules

The qualities of manufactured hard capsules will be better understood with the

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aid of characterizations. If the designed capsules have an appropriate likelihood of being used in a drug delivery system, their attributes might be compared to those of standard hard capsules. Good quality hard capsules should comply with the requirements according to international standards (Muhammad Al Rizqi *et al*., 2021). The tests done includes appearance of capsules, weight variation test, swelling degree test, water content analysis, disintegration test and dissolution test.

Results and Discussion

Antimicrobial Activity Test

Based on the results of the study, antimicrobial of synthetic konjac powder is very minimal and to get optimum results of antimicrobial, extraction of *Konjac Glucomannan* (KGM) from its plant is needed. There's a study by Zhifan Li *et al*, 2021 which conducts antimicrobial test on KGM with addition soluble green tea powder (SGTP) and found out that pure KGM alone does not exhibitsignificant antimicrobial activity against *S. aureus* and *E. coli.* The study also conducted the antimicrobial test by using commercial KGM and no antimicrobial activity was shown. Therefore, it is a possibility that plant extraction of glucomannan is needed to observe a good activity for antimicrobial of KGM.

Selection of Optimum Formulation

There were nine formulations produced, however only three of the formulations were chosen for characterization of capsule shells which were formulation F7, F8 and F9 (Table 1) while the other formulations were not selected due to various reasons (Table 2).

Weight Variation

Weight for formulation F7 was 0.2236 ± 0.00947 g, which was much higher compared to other formulations as well as the commercial capsules. This is probably due to F7 had a thicker shell compared to others since the solution was the most viscous. Considering there would be more total dissolved solids in the capsule solution after the drying process, a thicker capsule shell will have heavier weight (Iqbal *et al*., 2023). Nevertheless, all formulations complied to the standard where the deviation from the average mass is not more than 10% according toIP, BP and PhEur limit weight variation test for capsules for weight that is less than 300 mg.

Swelling Degree

Swelling degree test is done to determine capsule shell's ability to absorb water. Based on this investigation, it may be possible to determine if hard capsules dissolve more readily in water than other kinds (Muhammad Al Rizqi *et al*., 2021). As of right now, there is no recognized standard for the degree of swelling in the manufacturing of hard

Table 1: Formulations selected for characterization of capsules

Formulation	Appearance	Description
F7		• Hard • Very Thick • Formed capsule shape
F8		• Hard • Thin • Formed capsule shape
F9		• Soft • Thick • Deformed shape

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Table 2: Formulations that were not selected and the reasons

Ingredients (%)	Formulations					
	F1	F2	F3	F4	F5	F6
Konjac	4	6	8	5	4	7
Sorbitol	8	9	12	10	16	4
Starch	2	3	4	-	-	-
MCC	-	-	-	-	2	3
Lactose	-	-	-	-	-	-
Water	86	82	76	86	78	72
Appearance	Watery	Viscous	Viscous	Soft	Clumpy	Clumpy

capsules (Muhammad Al Rizqi *et al*., 2021). Among the formulations produced, F9 has the highest reading of swelling degree after the commercial capsule which is 332.163 ± 43.347 %. For this reason, it may be due to the amount of konjac powder which is used the most in formulation F9. It is believed that the swelling capacity will increase as the polymer concentration increases (Nuur Aanisah *et al.,* 2022). This is because hydrogen bonds induce interactions to form a network in the continuous liquid by limiting the junction zone between glucomannan molecules (Nuur Aanisah *et al.,* 2022). This claim could be supported by the increasing trend of konjac powder concentration in the formulations which leads to increase in degree of swelling for the capsules.

Water Content Analysis

Determining the moisture content is crucial since the amount of water in a hard capsule determines its stability and shelf life (Mohd Aiman Hamdan *et al*., 2021). Organic material is used to make capsule shells, which typically become overgrown with mold and fungi if they possess more than 20% water content (Mufrodi *et al*., 2019). There was no current specific requirement for konjac capsule's range for water content. According to USP, water content for hard capsules usually consists of 10-15%. All of the formulations did not comply to the range of water content specified, formulation F7 was lower than the range and F8 and F9 were slightly higher. The obtained result from this study showed that formulation F7 presented a much lower water content of 7.867 ± 0.570 % compared to F8 and F9 which were 17.653 ± 1.194 % and 16.65 ± 0.442 % respectively. These results may be affected by number of excipients incorporated in the formulation. Formulation F7 consisted of a greater amount of starch and sorbitol and smaller amount of distilled water compared to F8 and F9.

Disintegration Test

This disintegration analysis is important to determine the quality of a drug delivery and release of a drug of a drug at a certain time (Muhammad Al Rizqi *et al*., 2021). Disintegration time according to both IP and BP for hard capsules should not exceed 30 minutes. Therefore, all formulations complied to the specification and required less than 15 minutes to disintegrate. It should be noted that the disintegration times of different materials will vary. For instance, HPMC hard capsules disintegrate in 16 ± 5 minutes, while gelatin hard capsules will require 12 ± 4 minutes (Muhammad Al Rizqi *et al*., 2021). The disintegration time in water was influenced by the thickness of the capsule shell. As the thickness increases, the time taken for capsule to disintegrate in water completely also increases (Iqbal *et al*., 2023). From this study we could observe than the thickest formulation F7 had the slowest disintegration time of 12 minutes 30 seconds. Meanwhile, the commercial capsules have the thinnest shell compared to other formulations and had the faster disintegration time which is 6 minutes and 24 seconds.

Dissolution Test

In both citrate and phosphate buffers as dissolution medium, all capsules showed similar drug release trend (Figs 1 & 2). A study by Glube *et al*., 2013, finds that in

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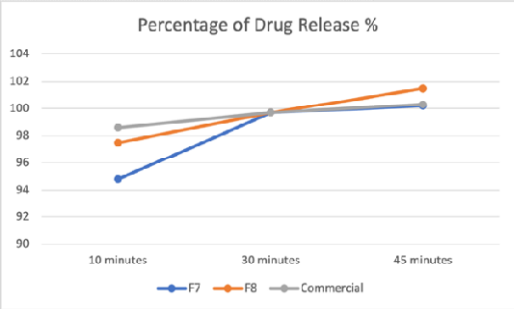

Fig. 1: Dissolution profile of formulation F7 & F8 compared to commercial capsule in citrate buffer over 45 minutes

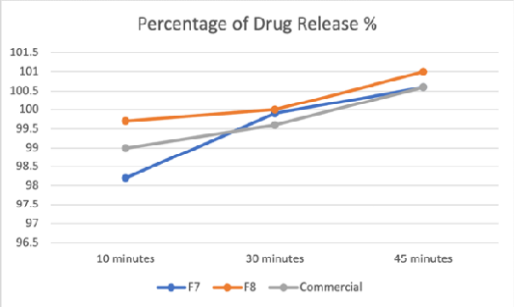

Fig. 2: Dissolution profile of formulation F7 & F8 compared to commercial capsule in phosphate buffer over 45 minutes

dissolution of gelatin and HPMC capsules, dissolution behavior at pH 6.8 (phosphate buffer) and pH 4.5 (citrate buffer) was similar to each other. It was observed that both formulation F7, F8 and commercial capsule was completely able to release drug at the 45th minute. For all results, 90% of the drugs was released at the 10th minute indicating a fast rate of drug release and high bioavailability. According to a study's findings by Iqbal *et al*., 2023, dye powder that was incorporated in capsule was released into the environment in less than five minutes by konjac and pectin capsule shells that were tested for dissolution test in an acidic solution.

According to results for characterization of capsule shells, F8 was selected as the best formulation as its characterization results fulfils the standard requirement. In the matter of appearance, formulation F8 was shaped with proper features and comparable to the commercial capsules. The result for weight variation test for formulation F8 was 0.0845 ± 0.00320g and none of the capsule's weight deviates by ± 10% from each other. Its swelling capacity was appropriate with the value of 116.400 ± 25.272% while the time taken for the capsules to disintegrate was 9.20 ± 0.557 minutes which was within the standard limit for hard capsules. In both dissolution medium, formulation F8 presented complete drug release within 45 minutes. However, F8 contains water content of 17.653 ± 1.194% which is slightly higher than the required range of 10-15%.

Conclusion

The study was done to observe antimicrobial properties of synthetic *Konjac Glucomannan* as well as to formulate hard-shell capsules by using *Konjac Glucomannan* as binder and analyze the properties of the capsules by running tests to ensure the capsules comply to international standards of hard-shell capsules. Based on the results of the study, antimicrobial of synthetic konjac powder is very minimal and to get optimum results of antimicrobial, extraction of *Konjac Glucomannan* from its plant is needed. It can also be concluded that hard capsule shells are able to be produced using *Konjac Glucomannan* with the presence of plasticizer and additional polymers such as starch and lactose to enhance the properties of the capsule formulation. There were nine formulations produced, however only three of the formulations were chosen which were formulation F7, F8 and F9. The best formulation that could be used in future studies would be formulation F8. This is due to it has the best properties in terms of appearance, weight variation, swelling degree, disintegration, and dissolution test. Almost all tests showed that F8 complied to all standards for hard shell capsule. However, F8 contains water content of which is slightly higher than the required range. In conclusion, the usage of *Konjac Glucomannan* as an

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alternative binder is appropriate in production of capsules with addition of other polymers such as starch and lactose.

Contribution

IAA, SUR and SAR designedtheexperiments.IAA carried out the experiment and analysis. IAA have written the initial draft. SAR, YKBS and DY have refined the manuscript. All authors have read and approved the manuscript.

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