

GELATIN IN HALAL PHARMACEUTICAL PRODUCTS

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ABSTRACT

Concomitantly, with the increase of the Muslim population in the world, *halal* awareness has been on the rise. A lot of *halal* industries have emerged nowadays, and among them are *halal* pharmaceuticals. However, with the advancement of technology, gelatin-based products have been widely developed and are being used in the pharmaceutical industry. Its *halal* status can thus be questionable (*mashbooh*). This paper aims to study the Islamic perspective on gelatin-based products in pharmaceuticals. The study uses a qualitative method which involves literature review from *al-Quran*, *as-Sunnah*, articles in journals, and other references from the internet that can be trusted as credible data sources. In addition, the methodology of this study includes researching the *istihalah* method and *fatwa* in Malaysia to determine the *halal* status of gelatin in pharmaceutical products. This paper also focuses on the Malaysian Standard of Halal Pharmaceuticals-General Requirements (MS 2424:2019) and the Malaysian Halal Certification Procedure Manual- Domestic 2020 (MPPHM 2020). The findings of this study show that gelatin mostly originate from animal sources. Therefore, its *halal* status can be questionable even if it comes from permitted animals such as cows or chickens. This is because the animals are only considered *halal* if they are slaughtered according to the precepts of Islamic law. In order to address such religious concerns, there have been a lot of research on the alternatives to animal gelatin such as from marine sources and plant-based sources. From the Islamic perspective, the use of gelatin from marine sources and animals that have been slaughtered according to Islamic rules is *halal*. However, gelatin which are sourced from pork and its derivatives are still *haram* after going the process of *istihalah* because its chemical substances remain the same and unchanged even after *istihalah*. Nevertheless, during an emergency, it may be permissible to consume medication containing pork gelatin if there is no replacement or alternative for pork gelatin even if it is from *haram* sources.

Keywords: *fatwa, gelatin, halal pharmaceutical, istihalah, Malaysia*

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Introduction

The Muslim population is almost one-quarter of the world population or approximately about 1.6 billion people. The huge Muslim population has led to an increase in awareness of *halal* pharmaceuticals. At the same time, *halal* products also have started to gain worldwide recognition as a new benchmark not only for their safety but also the quality assurance. In specific, *halal* products are not specified on food and beverages only, but it also covers cosmetic and personal care products as well as pharmaceuticals. *Halal* pharmaceuticals can be defined as drugs that are produced according to Islamic rules and conditions and contain only the permissible ingredients (Saha et al., 2019).

Next, *halal* can be defined as permissible things and lawful by Islamic law, whereas *haram* or non-halal means prohibited ones. In order to obtain the quality assurance of a *halal* product, it is not solely based on the principle of *halal* but the product itself should comply with the concept of *halalan toyyiban*. *Halalan toyyiban* is a concept that is deemed *halal* and contains wholesome ingredients which do not pose any health risk when the product is used (Sugibayashi et al., 2019). Hence, in *halal* pharmaceutical standards, it should fully comply with *halalan toyyiban* concept, including the source of all ingredients, safety, toxicity, manufacturing processes, and packaging up until the product reaches the consumer (Alzeer, 2021).

In the pharmaceutical industry, gelatin has been widely used especially in the production of capsule shells, tablets, granulation, and syrups (Rakhmanova et al., 2018). However, the *halal* status of gelatin-based products has been doubted as it usually comes from porcine sources, which is clearly *haram*. On the other hand, its *halal* status can also be questionable (*mashbooh*) even if it is from bovine sources as the slaughtering process should be done according to Islamic law (Jarita et al., 2020). Generally, in gelatin production, it is preferable to use porcine gelatin over bovine for several reasons. Therefore, *halal* gelatin production has become a challenge for Muslims globally as its production in the world is only projected to be less than 1% (Zamzahaila et al., 2020).

Therefore, in order to be globally recognized as Halal Hub, the Department of Islamic Development Malaysia (JAKIM) has been developing a *halal* certification system in Malaysia. JAKIM has been managing the administration of *halal* certification as well as monitoring the *halal* industry and its product to comply with Islamic principles as well as to meet the requirement of *halal* standards (Sa'adan & Norhidayah, 2017). In specific, for pharmaceutical products to obtain *halal* certification in Malaysia, there are the Malaysian Standard of Halal Pharmaceuticals- General Requirements (MS 2424:2019) and the Malaysian Halal Certification Procedure Manual- Domestic 2020 (MPPHM 2020) as the main guidelines to be followed. Thus, the guidelines from MS 2424: 2019 and MPPHM 2020 are among the important guidelines for producing *halal* pharmaceutical products in Malaysia.

Moreover, from the Islamic perspective, Muslims are prohibited to consume any *haram* or doubtful (*syubhah*) thing. In general, the *halal* status of gelatin-based products can be known through their sources. If the sources are from marine or permitted animals that have been slaughtered according to Islamic rules, then it is *halal*, whereas if it comes from pig and its derivatives or animals that have been slaughtered not in accordance with Islamic rules, then it is considered *haram*. However, in Islam, there is *istihalah* process which means changing material into another material through the process of mixing and creating new shapes that physically and contently differ. Basically, it is known as the principle of purifying impure objects (Alwi, 2020). Therefore, for pork gelatin production, this paper will review the *halal* status of it through *istihalah* methods and fatwa from Malaysia.

In brief, this paper is aimed to study the Islamic perspective on gelatin-based products in pharmaceuticals. This study uses the qualitative method to collect information from articles and journal sources. This paper discusses three main topics which are the notion of gelatin, *halal* pharmaceuticals in Malaysia, and gelatin-based products in pharmaceuticals from Islamic perspectives.

The Notion of Gelatin

Definition of Gelatin

Gelatin has been recognized as exceptional and unique among commercial hydrocolloids, fulfilling several functions with a wide range of applications in diverse industries. Gelatin is a protein generated from collagen, a naturally occurring protein found in mammals' tendons, ligaments, and tissues (M. Farahi et al., 2018).

Specifically, gelatin is a mixture of peptides and proteins that are made of collagen hydrolysis that comes from bone, skin, and connective tissue of animals such as pigs, cows, fishes, and chickens. Gelatin is mainly an unmodified hydrolyzed collagen in which the collagen protein is converted to smaller peptides. Gelatin has a wide molecular weight range in relation to physical and chemical methods of denaturation based on what kind of hydrolysis process is used in its production (Elyasi et al., 2020).

Apart from that, gelatin also has a unique amino acid composition and structure that provides functional properties (Amertaningtyas et al., 2019). Commonly, gelatin is used as a gelling agent in the food, pharmaceutical, photographic, and cosmetic industries (Elyasi et al., 2020). In particular, gelatin distinctive structure of amino acids is able to provide several medical benefits and the form of gelatin can vary. In particular, it can be in the form of tablets, granules, or powders, and sometimes it can be dissolved in water before being used (Alipal et al., 2021).

Gelatin which is manufactured from mammalian skin and bones is widely available all over the world (Nirwandar, 2021). It is a chemical substance that is dense, translucent, colorless, dried, and tasteless. It is a substance made from collagen fibers connecting tissue, skin, bone, and cartilage which are degraded using acids or bases. Besides, it also can be obtained from partial hydrolysis of collagen. Apart from that, gelatin also can act both as a gelling agent and a non-gelling agent because it is a soluble protein.

In general, there are three main stages in producing gelatin. The first stage is preparing the raw material, which includes the removal of non-collagen components. The second stage is the conversion of collagen into gelatin. The final stage is the purification and recovery of dry gelatin (Amertaningtyas et al., 2019).

In fact, there are two types of gelatins: Type A and Type B. Gelatin sources from type A are usually made from young animals, especially the skin of young pigs. On the other hand, gelatin sources from type B are usually made from cattle hides or bone. Type A gelatin is obtained using an acidic curing solution, such as solutions of hydrochloric acid, sulfuric acid, sulphurous acid, or phosphoric acid. The soaking of the curing process is rapid, and it usually takes 3 to 4 weeks. On the contrary, type B gelatin is obtained using a basic curing solution, such as solutions of lime (Ca(OH)₂) or NaOH, so the soaking or curing process requires more time and takes approximately 3 months, especially when using bone as the raw material (Amertaningtyas et al., 2019).

In short, gelatin is a protein generated from collagen, a naturally occurring protein found in mammals' tendons, ligaments, and tissues. Gelatin also has a unique amino acid composition and structure that provides functional properties which can be used in the food, pharmaceutical, photographic, and cosmetic industries. Generally, the process of gelatin production has three main stages. Apart from that, there are two different types of gelatins that are obtained from acidic curing solution and basic curing solution.

Sources of Gelatin and Its Alternatives

In general, animal sources have been used to produce gelatin and it basically comes from a variety of biopolymer raw materials. For instance, it comes from swine (pig), bovine (cow), poultry (chicken), ovine (sheep), and caprine (goat) (Zamzahaila et al., 2020). In fact, gelatin is mainly made from pigs or cows as they are more economical. However, the process of preparing gelatin from animal sources takes time and is costly. Hence, it is considered to be a major disadvantage of animal gelatin in terms of the

industry owing to its preparation ground requiring a considerable of time and money (Elyasi et al., 2020).

First and foremost, animal gelatin from swine. Swine gelatin is derived from the pig's skin, bone, and connective tissues. The only advantage of pig gelatin is its cost-effectiveness as well as the availability of its supplies and high breeding rates. If a sufficient herbal or chemical source for gelatin is discovered or produced, then this benefit can either vanish or dim. From a scientific view, pork has many pathogens and harms which can endanger humans. Furthermore, pork also has a very high level of cholesterol, while its lipids and uric acid are very harmful to humans. In the various studies that have been conducted, there is a strong relationship between pork consumption and gastric, prostate, breast, uterine, liver, and gallbladder cancer as well as other cancers. Thus, it can be said that the consumption of pork has been associated with many diseases in humans (Elyasi et al., 2020). Hence, it is not preferable to consume swine gelatin as it has many disadvantages except for its cost-effectiveness as well as the availability of the supplies.

Secondly, animal sources come from bovine. Bovine gelatin is derived from cow's skin, bone, and connective tissues. Bovine gelatin is also prepared just like swine gelatin, which has many of its properties and disadvantages. Bovine gelatin also has been widely used, but it still has a lot of mentioned risks especially if it is not slaughtered in an Islamic way as it can lead to religious concern for Muslim consumers. Moreover, several studies have suggested that the presence of bovine gelatin causes allergic responses (Elyasi et al., 2020). Apart from that, there is a shortage of bovine-based raw materials for pharmaceutical usage due to religious concerns. Furthermore, it is also having issues with the shortage of agricultural land, the emergence of disease, and also the shift in human consumption for health reasons (Mohd Shakrie et al., 2018).

Thirdly, animal sources from poultry. Poultry gelatin is derived from chicken and it has become a demand due to the switching of consumer preferences. This is because chicken meats are acceptable to most religions and there is a perception that poultry meat is healthier than other types of meat. Last but not least, animal sources from ovine and caprine. Ovine and caprine gelatin are derived from sheep and goats. They are considered as mammalian sources that can be used to obtain gelatin without any religious or even cultural barriers around the world (Elyasi et al., 2020). Nevertheless, in order to be approved for Muslim consumption, the gelatin from poultry, ovine and caprine sources must be slaughtered according to Islamic rules.

However, the demand for gelatin from animal sources has decreased due to many reasons. In particular, it is mostly due to religious concerns, shortage in agricultural land, the emergence of disease, and also the shift in human consumption for health reasons (Mohd Shakrie et al., 2018). In specific, a recent outbreak of mad cow disease, also known as BSE (Bovine Spongiform Encephalopathy), has resulted in a rise in demand for non-mammalian gelatins, as well as increased demand and interest in fish gelatin. Fish gelatin demand has surged due to Muslim consumers' need for gelatin that meets *halal* regulations. Regardless, the findings of many studies show that the quality of fish gelatin is not comparable to raw materials from cows and goats (Nirwandar, 2021). Particularly, fish gelatin is made from the skin and bones of fish with the goal of substituting for *haram* gelatin. This type of gelatin has its own set of limits and challenges. Moreover, as it is from fish sources, it has not always been readily available, and the fish itself is a valuable and expensive food that it is not economical to turn into gelatin (Elyasi et al., 2020).

Generally, there are no plant sources of gelatin, and there is no chemical relationship between gelatin materials referred to as vegetable gelatine (Zamzahaila et al., 2020). However, there are gelatin-like materials that are prepared from vegetable sources with different formulations. They have excellent qualities; they are often very useful and not allergenic because almost all of them are made of safe and non-allergenic polysaccharides. Moreover, the most important thing for herbal sources is that they are *halal*. So far, gelatin from plant sources that have been discovered as alternatives to animal gelatin is agar, pectin, konjac, and carrageenan (Alipal et al., 2021; Elyasi et al., 2020).

Firstly, is agar which can be figured out in a jelly-like substance similar to herbal gelatins. Most of the agar is made up of polysaccharide agarose, which is a supporting material found in the cell walls of some seaweed and is liberated when it is boiled. In general, agar is regarded as a healthy and helpful gelatin with no recorded allergic reactions or side effects; however, owing to its laxative properties, it is not recommended for persons who suffer from diarrhea. Therefore, despite its high benefits, it is still considered as less economically efficient due to the lack of resources (Zhang et al., 2020).

Secondly, in terrestrial plants, pectin is a structural heteropolysaccharide present in the main cell wall. Pectin is mostly made from orange peel and apple scum, which are both by-products of juice production. Animal gelatin manufacturing is slower and more difficult than pectin production. In humans, pectin has a strongly favorable effect on the intestines and excretion, and it can also be used to remove waste. Besides, pectin has a strong favorable influence on human intestines and excretion, as well as the ability to remove heavy metals from the body. Pectin has good drug-making characteristics, and it is presently utilized to make several drugs, such as pastille tablets. The World Health Organization and the American Food and Drug Administration both consider pectin to be safe (Elyasi et al., 2020).

Apart from that, there is konjac. Konjac is a plant in the *Araceae* family that is grown as a food in Japan, China, Korea, and Myanmar. This plant also contains konjac gelatin, a jelly agent that can be used as a vegetarian alternative to gelatin (Alipal et al., 2021). Glucomannan is used to make about 40% of konjac gelatin. This gelatin alone has many healing properties, including detoxification, tumor suppression, blood stasis alleviation, and phlegm smoothing. As Konjac gelatin is calorie-free and high in fiber, it is suitable for diabetics, obese individuals, diabetics, and a variety of other people. Nevertheless, one of the issues with Konjac gelatin is its edible size. As the jelly is not digested in the human body, it might induce choking among youngsters if they eat a large chunk of it.

Next, is carrageenan. Carrageenan is a carbohydrate derived from red algae that are edible. In the food business, carrageenan is a great gelatinizing agent because of its high binding power. Carrageenan is a protein-binding carbohydrate found in dairy and animal products. It is not utilized in pediatric digestible products and medications because of health risks and concerns (Elyasi et al., 2020).

To conclude, some religions and cultures forbid the use of gelatin derived from animal sources. For example, in the religion of Islam and Jews, eating gelatin made from swine source is prohibited. On the contrary, Hindus are known to be vegetarians who avoid using animal-based gelatin, particularly cow gelatin, because cows are sacred to them (M. Farahi et al., 2018; Elyasi et al., 2020). As a result, providing gelatin from *halal* sources has become a priority due to demand from consumer preference (Zamzahaila et al., 2020). Therefore, there is room for alternative gelatin sources which can be accepted especially for Muslims due to religious and cultural concerns (Mohd Shakrie et al., 2018), which can be deployed from marine and plant sources. Furthermore, gelatin derived from permitted animals such as cows, chickens, sheep, and goats also should be slaughtered in accordance with Islamic laws so that they can be considered *halal* and can replace the swine gelatin.

Pharmaceutical Uses of Gelatin

Gelatin has been used in the manufacture of pharmaceutical items since the 19th century, and possibly earlier. In fact, pharmaceuticals and nutraceuticals are the second and third largest application categories for gelatin after food. Respectively, the total market of gelatin in pharmaceuticals and nutraceuticals account for 26% and 21%, which imply a total of USD 1.3 billion market in 2015 (M. Farahi et al., 2018).

Pharmaceutical industries have widely used gelatin-based products in their production. In particular, gelatin is used as an excipient in a variety of medicinal dosage forms, including capsule shells in both hard and soft shells. Apart from that, tablets, suspensions, emulsions, and injections are all examples of dosage forms made from gelatin. Besides, due to its unique chemical features, gelatin is also used in pastilles, troches, microcapsules, suppositories, effervescent tablets, sub-coating agents, as well as an ingredient in wound care products (Mohd Shakrie et al., 2018). According to a report, the

pharmaceutical industry is using approximately 6% of the total gelatin production (Rakhmanova et al., 2018; Rahat, 2019).

In general, gelatin is omnipresent and it is used in a variety of pharmaceutical applications, including oral applications. For instance, gelatin is used in the production of hard or soft elastic capsule shells, tablet formulation, and disintegration agent that satisfies consumer concerns about the use of synthetic or chemically modified substances (Mohd Shakrie et al., 2018). Apart from that, gelatin is used as a plasma substitute during emergency surgery, water-insoluble absorbable gelatin film, pastilles, and troches which are usually being consumed to reduce cough. In addition, it is also used in bacteria growth media which acts as a useful diagnostic and research tool (M. Farahi et al., 2018).

In particular, gelatin substantially is significant in medicine, especially in the realm of hemostasis which can help in preventing bleeding. At the bleeding site, gelatin can behave as a stable clot. While expanding, gelatin particles might act as a site for a fibrin clot to develop around the bleeding site, limiting blood flow and forming a mechanically stable matrix (Alipal et al., 2021). Moreover, gelatin is also used in the pharmaceutical business to make granulation, and syrups since it is a natural coating material that is also readily digestible (Rakhmanova et al., 2018; Rahat, 2019; Zamzahaila et al., 2020).

However, oral gelatin consumption such as soft gel capsules, are commonly made from animal sources, which are derived mostly from animal skins, particularly pig skin and lard. As a result, gelatin capsules are not suitable for usage by persons who hold a strong religious conviction and refrained from eating particular animals for religious reasons (Zamzahaila et al., 2020). Therefore, the main issue regarding oral gelatin consumption in pharmaceuticals is due to religious reasons. Thus, in order to substitute porcine gelatin, there has been research conducted to explore the potential gelatin alternatives such as from fish, poultry, microbes, and plant-based sources like pectin, agar, and carrageenan (M. Farahi et al., 2018).

Next, in the medical industry, there are a lot of substances such as hydrogel, nanomicrosphere containers, nanofibers, pharmaceutical additives, and cell transplantation carriers that are made with gelatin. Apart from that, gelatin is also employed in the encapsulation of several pharmacological products due to its micro or nanoparticles. Gelatin is utilized as a matrix for intravenous infusions, injectable drug delivery microspheres, and implants in the medical and pharmaceutical industries (Alipal et al., 2021).

In specific, gelatin and trypsin are two important ingredients in the manufacturing of vaccines. Therefore, gelatin has become one of the most important substances in producing a vaccine. This is because gelatin is a protein that is isolated and utilised as a stabiliser in vaccines (Arieff et al., 2020). Hence, its presence is very important in the processing of quality and effective vaccines.

In brief, gelatin has a lot of uses in pharmaceutical industries and it has become one of the most important ingredients in the production of pharmaceutical products. For example, gelatin has been used in oral gelatin consumption such as hard or soft elastic capsule shells, tablet formulation, and disintegration agents. Therefore, gelatin is very important in the production of medicine in the pharmaceutical industry. On the other hand, gelatin is also one of the important substances in producing a vaccine as it is utilized as a stabilizer in vaccine production which can help its effectiveness.

Halal Pharmaceuticals in Malaysia

Definition of Halal Pharmaceutical

Nowadays, *halal* pharmaceuticals are one of the emerging *halal* industries. However, despite their large market and religious significance, these products are understudied and become a source of debate, particularly when it comes to the ingredients and the manufacturing method. The majority of pharmaceutical products on the market do not adhere to Halal Islamic guidelines, and there are only a few studies that have been undertaken in this field. Furthermore, the concept of *halal* in medicine has

yet to be investigated or presented to medical students or practitioners (Baker Ahmad et al., 2020). Thus, it is very important for pharmaceutical products to be studied, as *halal* pharmaceuticals have been one of the important *halal* industries around the world.

In general, *halal* pharmaceuticals can be defined as those that meet the requirement of Islamic laws (Baker Ahmad et al., 2020). Particularly, all drug products that are obtained from a permissible source are known as *halal* pharmaceuticals. It can come either from animals, plants, or organic or inorganic substances, as long as they are prepared, manufactured, and extracted according to Islamic guidelines. Apart from that, *halal* pharmaceuticals should not only be free from haram ingredients, but they should also need to be *tayyib*. The phrase is *tayyib* refers to a clean and pure product. Besides, the *tayyib* product also must be produced using standard processes and procedures. Thus, it can be said that pharmaceutical products must not only be *halal*, but also need to be considered as *tayyib* or clean from Islamic rules (Saha et al., 2019).

In specific, based on Malaysian Standard of Halal Pharmaceuticals- General Requirements (MS 2424:2019), *halal* pharmaceuticals were defined as pharmaceutical products that contain ingredients permitted under the *Shariah* law and *fatwa* which: a) Do not contain any parts or products of animals that are non-*halal* or any parts or products of animals which are not slaughtered according to *Shariah* law and *fatwa*; b) Do not contain *najs* according to *Shariah* law and *fatwa*; c) Safe and efficacious for human use according to prescribed dosage, of quality and hygiene; d) Not prepared, processed or manufactured using equipment contaminated with *najs* according to *Shariah* law and *fatwa*; e) Do not contain any human parts or its derivatives that are not permitted by *Shariah* law and *fatwa*; f) During the preparation, processing, handling, packaging, storage and distribution, the *halal* pharmaceutical products are physically segregated from any other pharmaceutical products that do not meet the requirements stated in items a), b), c), d), e) or any other items that have been decreed as non-*halal* and *najs* by *Shariah* law and *fatwa* (Department of Standards Malaysia, 2019; Johari et al., 2021).

In Malaysia, *halal* drugs must adhere to the Drug Control Authority's laws and regulations, which is regarded as a leader in *halal* standards (Baker Ahmad et al., 2020). In fact, both of Malaysian Standard of Halal Pharmaceuticals- General Requirements (MS 2424:2019) and Manual Procedure for Malaysia Halal Certification- Domestic 2020 (MPPHM 2020) emphasize that every pharmaceutical product must be registered with the Drug Control Authority (DCA) from the Ministry of Health Malaysia which include prescription and non-prescription medicinal drugs in completed dosage forms for human usage (Department of Standards Malaysia, 2019; Department of Islamic Development Malaysia (JAKIM), 2020). Therefore, in Malaysia, it is very important for the applicant of *halal* pharmaceutical products to register with the Drug Control Authority.

Apart from that, *halal* pharmaceuticals also must comply with MS 2424:2019. This is because the Malaysian Standard from MS 2424:2019 acts as a general guideline denoting the production, handling, and storage of *halal* pharmaceutical products which has been gazetted by the Government of Malaysia (Johari et al., 2021). Therefore, *halal* pharmaceuticals are not focused only on the ingredients, but also on the whole process starting from the preparations until the distribution of pharmaceutical products. This is because the medicine can be contaminated with non-*halal* materials throughout the process, making it prohibited (*haram*) (Ernawati, 2019). Hence, it is important for pharmaceutical products to be monitored from the beginning of their preparation up until their distribution to the consumers based on the guidelines from MS 2424:2019.

Furthermore, MS 2424:2019 also mentions that the types of pharmaceutical products are varied. To illustrate, pharmaceutical products include biopharmaceuticals such as vaccines, recombinant products, monoclonal antibody products, and gene therapy products. Next, they also include radiopharmaceuticals, health supplements, traditional medicines, and investigational medicinal products (Department of Standards Malaysia, 2019).

In short, *halal* pharmaceuticals can be defined as pharmaceutical products that contain ingredients permitted under the *Shariah* law and *fatwa*. However, pharmaceutical products must not only be *halal*, but also need to be considered as *tayyib* or clean from Islamic rules. In Malaysia, MS 2424:2019 has

been a general guideline for *halal* pharmaceutical products which mentions the detailed description of the production, handling, and storage of *halal* pharmaceutical products. Generally, pharmaceutical products are varied, and include biopharmaceuticals, radiopharmaceuticals, health supplements, traditional medicines, as well as investigational medicinal products.

Halal Certification for Pharmaceutical Products in Malaysia

In Malaysia, the product that has been certified should be in accordance with Malaysian *halal* standardization. This is to ensure its *halal* assurance. There are two assurance instruments that have been developed in this country as a result of numerous rules. They are the Malaysian Standard and Malaysian Halal Certification Procedure Manual. They serve as practical guidelines for *halal* product certification in Malaysia (Ahmad Hasan et al., 2020). In specific, the guidelines for pharmaceutical products in Malaysia are Malaysian Standard of Halal Pharmaceuticals- General Requirements (MS 2424:2019) and Manual Procedure for Malaysia Halal Certification- Domestic 2020 (MPPHM 2020).

Halal certification is a commercial approach that is viewed as a value-added component because the primary criterion for all medications are their safety and effectiveness. Therefore, all drugs must be registered with the appropriate government before being certified *halal* (Department of Standards Malaysia, 2019). *Halal* certification is vital for certifying what is *halal* and what is not. Hence, the process of verifications that begins with the raw material and ends with the final launch of the product or service can be very complex. According to a Malaysian study on *halal* certifications, one of the current issues is that there are no international standards for the *halal* industry. Thus, unifying *halal* industry norms and developing a consistent framework would undoubtedly add value to all sectors of the industry (Baker Ahmad et al., 2020).

At the federal level in Malaysia, the Department of Islamic Development Malaysia (JAKIM) plays a key role in *halal* certification issues. JAKIM is assisted in its role as *halal* authority by a number of institutions, including the State Islamic Religious Department (Jabatan Agama Islam Negeri termed hereafter as JAIN) or State Islamic Religious Councils (Majlis Agama Islam Negeri hereafter termed as MAIN), other government departments such as the Ministry of Health as well as non-government organisations (NGO), *halal* centres, and local universities (Mohd Zabidey et al., 2017; Rokshana, 2017). Commonly, JAKIM and JAIN undertake the certification procedure in the same way and follow the same guidelines as the newest *halal* certification guideline which is Manual Procedure for Malaysia Halal Certification- Domestic (MPPHM) 2020. This document serves as a general guideline that outlines the standards and procedures that must be followed by all organisations participating in the Malaysian *halal* certification system (Mohd Zabidey et al., 2017).

The MPPHM was issued by the JAKIM, JAIN, and MAIN to clarify the requirements that must be met by the Malaysian *Halal* certification administrator. It covers nine aspects of *halal* certification, including pharmaceuticals. To obtain a *halal* certificate from JAKIM or JAIN, those must meet the following conditions (Ahmad Hasan et al., 2020; JAKIM, 2020).

Generally, applicants begin the process of obtaining the *halal* certification by submitting an application to the *halal* certification bodies. Food and beverages products, cosmetic and personal care products, pharmaceutical products, food premise and hotel, consumer goods, logistic services, slaughterhouse, contract manufacturing or Original Equipment Manufacturer (OEM) and also medical device products are the nine certification schemes offered by JAKIM in Malaysia. Before going through the *halal* inspection procedure, the application will be evaluated and confirmed by *halal* certification bodies together with the accompanying documentation. The application, along with the findings or evidence of compliance acquired during the *halal* inspection process, will then be presented to the Halal Certification Panels. This is the procedure for approving or rejecting the application. Once the application has been approved, the *halal* certification applicant will be given a Halal Certificate and a Halal Logo. After the applicant or Halal Certificate holder receives the certificate, they will be supervised by *halal* certification bodies that are subject to specified categories, methods, and conditions to guarantee that they always fulfil the certification requirements and standards (Mohd Zabidey et al., 2017; JAKIM, 2020).

Specifically, in term of *halal* certification for pharmaceutical products in Malaysia, the basic references for *halal* pharmaceutical products in Malaysia are Malaysian Standard of Halal Pharmaceuticals-General Requirements (MS 2424:2019), Pharmaceutical Inspection Co-operation Schemes (PICs), National Fatwa Council for Islamic Affairs decisions or *Fatwa* decreed by the states, and other acts, regulations, standards, and related guidelines. Apart from that, management responsibility for multinational category applicants must establish an Internal Halal Committee in accordance with the Malaysia Guidelines for Halal Assurance Management System 2020 which is to appoint a Halal Executive and hire at least two Muslim workers on a permanent basis from Malaysian citizen with knowledge of the halal management system and work fulltime in the handling or processing of pharmaceutical section. In addition, the applicant must establish a Halal Assurance System in accordance with the Malaysian Guidelines for Halal Assurance System (Ahmad Hasan et al., 2020; JAKIM, 2020; Johari, 2020).

Based on pharmaceutical product schemes from MPPHM 2020, every pharmaceutical product must be registered with the Drug Control Authority (DCA). Premises that process and produce pharmaceutical products must have a Manufacturer's License from the National Pharmaceutical Regulatory Agency (NPRRA) and meet the requirements of Good Manufacturing Practices (GMP). Pharmaceutical products that are eligible for *halal* certification must follow the following categories, which are: scheduled poison products; non-toxic products or over-the-counter; health supplement products; or natural products such as traditional and complementary medicines. Apart from that, each pharmaceutical product must be registered with the MS 2424: 2019, Halal Pharmaceuticals-General Requirements (First Revision), Sale of Drugs Act 1952, Control of Drugs and Cosmetics Regulations 1984, Drug Registration Guidance Document (DRGD) and other legislation and the latest regulations enforced by the relevant authorities shall be complied with (JAKIM, 2020).

Therefore, the applicants or producers of pharmaceutical products must guarantee that the product has been registered and has received an approval letter or registered products from the National Regulatory Pharmaceutical Agency (NPRRA) of the Ministry of Health Malaysia in order to receive *halal* certification (Johari, 2020; Johari et al., 2021). In particular, the regulatory control of pharmaceutical products and traditional medicines in Malaysia is carried out by the NPRRA. It is an institution under the Pharmaceutical Services Division (PSD) Ministry of Health, which ensures the quality, efficacy, and safety of pharmaceutical products as well as the quality and safety of traditional medicines and cosmetics market in Malaysia. On the other hand, the Drug Control Authority (DCA) is the executive authority established under the Control of Drugs and Cosmetics Regulations of 1984. This Authority's primary responsibility is to ensure the safety, efficacy, and quality of pharmaceuticals, traditional medicines, health supplements, veterinary products, and personal care products sold in Malaysia (Malaysian Investment Development Authority (MIDA), 2020).

Apart from that, the *halal* certification system evaluates and verifies items or services to ensure they meet *halal* requirements and *Shariah* guidelines or Islamic law. The *halal* certification bodies use the *halal* certification process to ensure that every procedure used in the creation of services and products complies with Islamic law (Mohd Zabidey et al., 2017). In addition, the use of the *halal* logo on pharmaceutical labels will be prohibited, except for over-the-counter products, traditional products, dietary supplements, and cosmetics that have been certified and approved as *halal* by JAKIM (MIDA, 2020).

To sum up, *halal* certification is a commercial strategy that is considered a value-added component because the basic criterion for all pharmaceuticals is their safety and effectiveness. In order to acquire *halal* certification in Malaysia, the certified product must adhere to Malaysian *halal* standardisation. There are two assurance instruments that have been developed for *halal* pharmaceutical products in Malaysia which are MS 2424:2019 and MPPHM 2020. In Malaysia, JAKIM plays a key role in *halal* certification issues. JAKIM is assisted in its role as the *halal* authority by several institutions, including JAIN or MAIN, other government departments such as the Ministry of Health as well as NGOs, halal centres, and local universities. In particular, JAKIM, JAIN, and MAIN issued the MPPHM to define the conditions that must be met by the Malaysian Halal certification administrator. Based on pharmaceutical product schemes from MPPHM 2020, every pharmaceutical product must be registered

with the Drug Control Authority (DCA). Besides, each pharmaceutical product must also be registered in accordance with MS 2424: 2019, Sale of Drugs Act 1952, Control of Drugs and Cosmetics Regulations 1984, Drug Registration Guidance Document (DRGD), and other relevant legislation and regulations.

Gelatin-Based Products in Pharmaceuticals from Islamic Perspectives

The Status of Gelatin in Islam

Nowadays, the *halal* pharmaceutical industry has become one of the most important *halal* industries in the world due to the collective consciousness of the world's Muslims to adopt religious teachings. As a result, the *halal* industry which also includes *halal* pharmaceuticals has now become a global trend (Nirwandar, 2020). However, one of the main issues that occur in *halal* pharmaceuticals is to obtain the *halal* status for its product as commonly, the ingredients of pharmaceuticals products mostly come from questionable (*mashbooh*) ingredients. In particular, gelatin is one of the questionable ingredients that has been widely used for pharmaceutical products.

In specific, porcine, and bovine gelatin are statistically the first and second most common sources of gelatin (M. Farahi et al., 2018). Therefore, for Muslim believers, it has become an issue as porcine is the most common source of gelatin on the international market. Hence, the need for *halal* gelatin which acts as a substitute for porcine gelatin has become essential for Muslim consumers. Commonly, alternatives for *halal* gelatin can be derived from poultry, marine, or plant-based sources (Zamzahaila et al., 2020). Therefore, the alternative source for porcine gelatin has become a preference of Muslim consumers as in Islam, all the pig and its derivatives are prohibited to be consumed.

From Islamic perspective, it is very important to consume what is *halal* and good for human consumption. This is because as stated in the al-Quran from verse 168 of Surah al-Baqarah: "*O mankind, eat from whatever is on earth (that is) lawful and good and do not follow the footsteps of Satan. Indeed, he is to you a clear enemy*". This verse emphasises that *halal* does not just subject to Muslims, but also to all people (Nirwandar, 2020). Apart from that, the principle of *Usul al-Fiqh* also emphasized that "*the law of origin of all things is lawful unless there is a prohibited statement*". Therefore, from this rule, it can be concluded that things remain lawful until there is another statement that prohibits its consumption. Hence, the things that Allah has silenced which can be questioned are lawful to be consumed as it is part of Allah's mercy (Alwi, 2020). Thus, in general, gelatin can be consumed and is lawful for Muslim consumption except if it comes from pig sources as well as the animal which are not slaughtered according to Islamic laws.

Generally, there are three terms to label the status of a product which are *halal*, *haram* and, *syubhah* or *mashbooh*. In specific, *halal* refers to what is permissible and lawful whereas *haram* refers to what is not permissible and illegitimate. On the other hand, *syubhah* or *mashbooh* refers to what is doubtful and should be avoided. In Islam, *halal* products that have been tainted with substances derived from questionable sources are preferable to be avoided based on *as-Sunnah*. Based on Sahih Bukhari 52, Sahih Muslim 1599, Prophet Muhammad ﷺ said: "*Verily, the lawful (Halal) is clear and the unlawful (Haram) is clear, and between the two of them are doubtful matters about which many people do not know. Thus, he who avoids doubtful matters clears himself in regard to his religion and his honour, and he who falls into doubtful matters will fall into the unlawful as the shepherd who pastures near a sanctuary, all but grazing therein. Verily, every king has a sanctum, and the sanctum of Allah is his prohibitions. Verily, in the body is a piece of flesh which, if sound, the entire body is sound, and if corrupt, the entire body is corrupt. Truly, it is the heart.*" (Zamzahaila et al., 2020). Therefore, in Islam, we are encouraged to consume *halal* products only and avoid from consuming any of *haram* or *syubhah* products.

However, in the status of gelatin consumption, it is considered as *syubhah* or *mashbooh* as it mainly comes from animal sources. Therefore, its *halal* status can be questionable. This is because as stated in al-Quran from verse 173 of Surah al-Baqarah: "*He has only forbidden to you dead animals, blood, the flesh of swine, and that which has been dedicated to other than Allah.*". In this verse, Allah has prohibited the carcass which refers to any dead animal, blood, and pork for Muslim consumption.

Therefore, any meat which refers to the pig and its derivatives as well as any animals that were slaughtered without reciting the name of Allah are prohibited to be consumed (Elyasi et al., 2020). However, as the primary source is from animals and particularly it comes from pig sources, therefore it is considered as *mashbooh*.

In particular, even if the gelatin comes from *halal* sources such as cows and poultry, but its slaughtering process must be checked in accordance with Islamic rules. This is because the main issue for the permitted animal sources is the slaughtering process as the animals may be slaughtered without reciting the name of Allah. However, marine, and plant-based sources are the best alternatives source for gelatin as its ingredients has a *halal* guarantee (Saha et al., 2019; Alwi, 2020). Thus, it can be said that the source of gelatin's raw materials is questionable if it is based on permitted animal sources such as cow, chicken, or goat. However, it does not become an issue if it comes from marine or plant-based sources and it can be considered as *halal*. On the other hand, if the gelatin is derived from pig sources, then it is surely haram. This is because as stated in al-Quran from verse 173 of Surah al-Baqarah, Allah expressly forbids the pork and its derivatives for Muslim consumption (Saha et al., 2019; Elyasi et al., 2020).

However, the status of pork gelatin can be changed through the *istihalah* process. Based on the terminology from Qal'ahji in Mu'jam Lughah al-Fuqaha', he stated that "*istihalah* is stated as non-reversible transformation". On the other hand, al-Zuhayli who is one of *fiqh* scholars has defined *istihalah* as "an exchange of the origin material into other condition or state either the origin is pure or impure (*najs*)."¹ (Muneer Ali et al., 2018; Halimah et al., 2020). In other words, *istihalah* can be defined as a conversion process that occurs in a substance with or without the addition of foreign matter, resulting in the development of a new substance with a different physical, chemical, or both physical and chemical appearance (Halimah et al., 2020; Muhammad Hanif, 2020). In *istihalah* process, it has three elements which are: raw material, conversion agents, and finish product. Specifically, the mixing process occurs as a result of natural or artificial interaction between the raw material and the conversion agent. After that, the finished product will next go through a conversion process that is physically and chemically distinct from the original material (Muhammad Hanif, 2020).

In *istihalah* process, some Muslim scholars have different opinions. The first group of scholars who accept *istihalah* application are from the *madhab* of Hanafi and Maliki with other contemporary scholars like Ibn al-'Arabi, Ibn al-Qayyim, al-Syawkani and Ibn Hazm al-Zahiri agreed with Ibn Taymiyyah as it solved uncertain things or new issues arises. Based on the opinion of Ibn Taymiyyah, stated that "the origin of every substance is pure until it is clear the substance is *najs*. Therefore, according to him, *istihalah* is more appropriate to be applied in this research because it widened the scope of the transformation process in the case of gelatin-based products as it involves multiple treatments chemically and physically that are important to contemporary developments. On the other hand, according to the Hanafi, Maliki, and Ibn Hazm schools of jurisprudence, *istihalah* is defined as a procedure that allows unclean substances to turn into something clean, either naturally or via the use of a transformation agent, method, or tools. Therefore, Ibn Hazm stated that the *istihalah* method is sufficient as long as the original component has changed its shape (Halimah et al., 2020; Muhammad Hanif, 2020).

However, the second group does not accept *istihalah* applications. Among them is Ibn 'Abidin, the *madhab* of Shafi'i and Hanbali, al-Nawawi, al-Syarbini and al-Qarafi. According to the Shafi'i and Hanbali *madhabs*, impure things do not become clean by changing their nature. However, they only accept natural transformation without any help from the transformation agent in the *istihalah* process. Based on the Shafi'i *madhab*, something haram can only be converted to halal under three circumstances: wine that naturally changes into vinegar, dead animal skin (excluding dogs and pigs) that becomes pure after tanning, and something that transforms into a new life, such as larvae from a cadaver (Halimah et al., 2020; Muhammad Hanif, 2020). In conclusion, the chosen opinion (*rajih*) is from the first group, which states that unclean things are purified if they are undergone the *istihalah* process (Muneer Ali et al., 2018).

Apart from that, the *istihalah* process also can be categorized as *istihalah sahahah* or *istihalah fasidah*. *Istihalah fasidah* is a process where it already reaches a complete transformation, whereas *istihalah sahahah* is a process that does not reach complete transformation (Halimah et al., 2020). Based on

istihalah sahihah, any changes made from the raw material until the finished product, whether in chemical, physical, or both of physical and chemical appearance are deemed *halal*. However, if we apply the actual notion of *istihalah*, we can see that gelatin which is obtained from any animal source undergoes physical but not chemical transformations. As a result, the *istihalah* method cannot be applied completely as it does not reach a complete transformation. Hence, the *istihalah* process of gelatin is clarified as *istihalah fasidah* (Halimah et al., 2020; Muhammad Hanif, 2020). Therefore, if it does not completely change through the *istihalah* process, then it remains haram and it is prohibited to consume it (Abdul Karim, 2018).

In brief, gelatin-based products are considered *mashbooh* because it mainly comes from animal sources and their raw materials and their slaughtering process can be questionable. On the other hand, pork gelatin is surely haram as it is derived from pig and it is prohibited to be consumed. However, after pork gelatin has undergone the *istihalah* process, its status has changed to a clean and pure substance, but at the same time, pork gelatin still remains haram and it is forbidden to consume it as it is part of *istihalah fasidah* that its finished product does not undergo a complete transformation. As for the issue of *istihalah*, there are two different opinions from Muslim scholars. The first opinion is from the *madhab* of Hanafi and Maliki who accepted the application of *istihalah* and the second opinion which is from the *madhab* of Shafi'i and Hanbali has rejected the application of *istihalah* except for three conditions.

Fatwa in Malaysia Regarding the Use of Gelatin in Pharmaceutical

In Malaysia, a *fatwa* institution is a body that deals with the administration of law on matters relating to Islam. In particular, there are two entities that issued *fatwas* in Malaysia which are the National Fatwa Committee for Islamic Religious Affairs Malaysia which is at the national level, and the Mufti Department in each state. A mufti serves as the leader of the Islamic religion and leads discussions about religious law in each of the 14 *fatwa* organisations that represent each state. In specific, according to Article 14 of the Rules of the National Council for Islamic Religious Affairs Malaysia, the National Fatwa Committee is responsible for considering, deciding, and issuing fatwas on any matter relevant to Islam brought to it by the Conference of Rulers. After that, the committee will present its findings to the National Council for Islamic Religious Affairs Malaysia (MKI), which will subsequently forward them to the Conference of Rulers with recommendations (Zulfaqar, 2019). Therefore, the duty of the National Fatwa Committee is generally to decide any religious issues that happened in Malaysia.

At the same time, MS 2424:2019 which explains guidelines for *halal* pharmaceuticals in Malaysia are also based on the *Shariah* and *fatwa* requirements that are incorporated into *halal* standards (Department of Standards Malaysia, 2019). In particular, *Shariah* law in Malaysia is the laws of Islam based on *madhhab* of Shafi'i or other *madhhabs* from *Hanafiah*, *Malikiah* and *Hanbaliah*, that have been approved by the *Yang di-Pertuan Agong* to be in force in the Federal Territory, or the Ruler of any state to be in force in that state within Malaysia. On the other hand, a *fatwa* is referred to as any religious decision that is validated by an authority associated with Islam and recognized by the *Yang di-Pertuan Agong* to be in effect in the Federal Territory, or by the ruler of any state to be in force in that state within Malaysia (Johari et al., 2021). To conclude, both *Shariah* law and *fatwa* are important in determining *halal* requirements for pharmaceutical products in Malaysia.

In particular, the National Fatwa Committee also issued a *fatwa* regarding the use of gelatin. However, the issue with gelatin is that it comes from animal sources and mainly is derived from swine origin. Therefore, gelatin is considered a questionable or *mashbooh* substance utilized in pharmaceutical products. In the general rule, Muslims must investigate the source of gelatin before using it. However, in extreme and emergency circumstances, such products may be used to save one's life (Widya, 2021). This statement is in accordance with the decision of the National Fatwa Committee in Malaysia. In specific, the National Fatwa Committee reviewed the issue of gelatin in medicine, in its 8th meeting on the 24th and 25th of September 1984 which concluded that the use of gelatin in medicine is now mandatory during emergency situations. However, if a *halal* component exists which can protect the drug or any pharmaceutical products from being degraded quickly, gelatin is no longer required in them (Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan, 1984; Zulfaqar, 2019). Therefore, the use of pork gelatin is prohibited except for emergency situations. However, if there are any *halal* alternatives to

substitute pork gelatin, then the consumption of *haram* substances from pork gelatin remains prohibited for Muslim consumption.

Besides, as for the pork gelatin that has undergone the *istihalah* process, the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia and the Fatwa Committee Meetings of the States who adhere to the Shafi'i madhab's fatwa has rejected the application of *istihalah* in the gelatin. Therefore, the acceptance of the *istihalah* process in gelatin production may be difficult to accept except in emergency situations (Mohd Hapiz & Muhammad Rahimi, 2017). In particular, the basis for the National Fatwa Committee's rejection of the *istihalah* has its justification, particularly in terms of the *istihalah*'s validity as well as ensuring that the production of halal products is not abused by manufacturers and operators of products by inserting illegal substances for double profits. However, the rejection of the application for *istihalah* does not reduce the space for Muslims to use it as it can be utilised in an emergency or *darurah* based on *Usul al-Fiqh* principle *al-darurat tubihu al-mahzurat* or "necessities permit the prohibitions". At the same time, the consumption of haram substances or "muharammat" such as pork gelatin during an emergency need to comply with another *Usul al-Fiqh* principle which is *al-darurah tuqaddaru bi qadariha* or "necessities are judged on its degree" (Mohd Hapiz & Muhammad Rahimi, 2017).

Conclusion

Halal pharmaceuticals is generating a lot of interest among Muslims and even non-Muslims due to the emergence and active progression of the *halal* industry around the world. However, there are a lot of issues that need to be addressed in the process of obtaining *halal* status for pharmaceutical products. Gelatin is one of the critical ingredients that has been widely used in pharmaceutical products. From the Islamic perspective, gelatin-based products are considered *mashbooh* as it comes from animal sources, and their raw materials and the slaughtering process can be questionable. In order to obtain halal certification in Malaysia, the applicant for halal pharmaceutical products must follow the guidelines from MS 2424:2019, MPPHM 2020, and register their products with the Drug Control Authority.

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