

## **HALAL CERTIFICATION PROCEDURE IN MALAYSIA AND INDONESIA: A STUDY ON CRITERIA FOR DETERMINATION OF HALAL PHARMACEUTICAL PRODUCTS**

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**Abstract:** Pharmaceutical products deals with different component of materials or substances and its whole process are more critical than food products. Malaysia has launched and implemented the Malaysian Standard MS 2424:2012 *Halal* Pharmaceuticals-General Guidelines since 2012 on *halal* pharmaceuticals and to the pharmaceutical manufacturers. The government of Indonesia also making *halal* labelling on all products mandatory in Indonesia by 2019. This momentum of *halal* certification for pharmaceutical products by both countries need to be enhance by improving the initiatives the implementation of standard and guidelines. The objectives of the study are to explain the concept of *halal* pharmaceuticals based on *halal* certification procedure in Malaysia and Indonesia, to examining the evidence from the Holy Al-Quran, *as-Sunnah* and *dalil* due to the determination of *halal* pharmaceuticals products, to analyse general principles based on Islamic law to the determination of *halal* pharmaceutical products and to identify a new method based on Islamic principles in determining the *halal* pharmaceutical products. In general, the qualitative method is used in this study, the data collection methods are through document analysis. The findings of this study. First, in understanding the concept of *halal* pharmaceuticals in Malaysia and Indonesia it is basically not only based on Islamic law alone, but also subject to the criteria and regulations enforced in both countries. Second, the Islamic principle of *halal* and *haram*, *darurah* and *fatwa* is a basis or general Islamic principle applicable to determine *halal* pharmaceuticals products. Third, the comprehensive method or criteria for determination of *halal* pharmaceutical products is encompassing the principle of pharmaceuticals derived from *halal* substances, materials, the principle of *Maslahah*, the principle of *Ihtiyath* and the principle of *Istihalah Tammah*.  
**Keywords:** Halal Certification, Pharmaceuticals Determination, Halal Product in Malaysia and Indonesia

**Abstrak:** Produk farmasi berkaitan dengan komponen bahan atau zat yang berbeda dan seluruh prosesnya lebih penting daripada produk makanan. Malaysia telah meluncurkan dan menerapkan Standar Malaysia MS 2424:2012 Pedoman Umum Farmasi Halal sejak 2012 tentang obat-obatan halal dan kepada produsen farmasi. Pemerintah Indonesia juga mewajibkan pelabelan halal pada semua produk di Indonesia pada 2019. Momentum sertifikasi halal untuk produk farmasi oleh kedua negara perlu ditingkatkan dengan meningkatkan inisiatif penerapan standar dan pedoman. Penelitian ini bertujuan untuk menjelaskan konsep kehalalan obat berdasarkan prosedur sertifikasi halal di Malaysia dan Indonesia, mengkaji dalil-dalil dari Al-Qur'an, As-Sunnah dan dalil karena penentuan

produk obat halal, menganalisis prinsip-prinsip umum berdasarkan hukum Islam untuk penentuan produk farmasi halal dan untuk mengidentifikasi metode baru berdasarkan prinsip-prinsip Islam dalam menentukan produk farmasi halal. Artikel ini menggunakan metode penelitian kualitatif, dengan metode pengumpulan datanya melalui analisis dokumen. Temuan dalam artikel ini adalah, pertama, dalam memahami konsep kehalalan farmasi di Malaysia dan Indonesia pada dasarnya tidak hanya berdasarkan syariat Islam saja, tetapi juga tunduk pada kriteria dan peraturan yang berlaku di kedua negara. Kedua, syariat Islam tentang halal dan haram, darurat dan fatwa merupakan dasar atau prinsip umum Islam yang berlaku untuk menentukan kehalalan produk farmasi. Ketiga, metode atau kriteria yang komprehensif dalam penetapan kehalalan produk farmasi meliputi prinsip kehalalan obat yang berasal dari zat, bahan, prinsip mashlahah, prinsip ihtiyath dan prinsip istihalah tammah.

**Kata Kunci:** Sertifikasi Halal, Penetapan Farmasi, Produk Halal di Malaysia dan Indonesia

## Introduction

Nowadays, there has been an awareness raised on *halal* among Muslim and non-Muslim countries, that need to fulfill their domestic Muslim market as well to expand into the global markets. In Malaysia and Indonesia, the *halal* certificate and logo are an authoritative and independent testimony to one's claim as a manufacturer, producer or distributor of *halal* products. For the consumers, it is a symbol of assurance and confidence. Malaysian and Indonesia *halal* certification system plays an important part in creating harmony among its various multi-racial population thus provides security and prosperity to the country. In short, *halal* certification not only has economic implication but social as well. These two countries are also known as pioneers in developing and promoting the *halal* certification system and becomes a role model for other nations.

The word *halal* has been mentioned many times in the Holy Al-Quran, regardless to the variety of its versions. This fact is clearly stated in verse 168 of Surah Al-Baqarah which means: "O mankind! Eat of what lawful and good on earth, and do not walk in Satan's footsteps, for he is an open enemy for you". According to Ibn Manzur's view, the sentence "*Halal*" is a published word derived from the basic word *halla*, *yahillu*, *hillan* (حلا يحل حلا) which brings meaning out of something that is unclean.<sup>1</sup> In fact, these words are often referred to and used by the Islamic community, although in non-Arab circles in various contexts. The Malaysiana Encyclopedia defines *halal* as Arabic words intended to be justified or allowed. In the case of diet and food, most are considered *halal*, but these cases are specifically stated in the Holy al-Quran and the *Hadith*. Humans must not at all say *haram* to the *halal*. Likewise it is forbidden to say *halal* to the unlawful one or *haram*.<sup>2</sup>

The concept of *halal* applies to pharmaceutical products as well. *Halal* certification scheme for pharmaceuticals is needed to inform Muslim consumers or Muslim patients that products are prepared by *halal* methods. Through the *halal* certification system, *halal* products can be identified. Pharmaceutical is connected with the production of medicines and drugs or pharmaceutical companies.<sup>3</sup> The term and definition given in Malaysian Standard MS 2424 for pharmaceuticals is pharmaceutical products in finished dosage

1 Jamal al-Din Muhammad al-Ansori Ibn Manzour, *Jamal Al-Din Muhammad Al-Ansori* (Dar al-Misriyyah wa al-Tarjamah), 173.

2 Ensiklopedia Malaysiana, Anzagain Sdn.Bhd.(1996), Vol. 5, Page. 254.

3 New Oxford English English Malay Dictionary, (Second Edition), (Selangor: Oxford Fajar, 2012), Page. 617.

forms, including both prescription and non-prescription medicinal products for human use which are registered with the Drug Control Authority, Ministry of Health Malaysia.<sup>4</sup> Examples may include biopharmaceuticals (including vaccines, recombinant products, monoclonal antibody products, gene therapy products etc), radiopharmaceuticals, health supplements, traditional medicines and investigational medicinal products. while, *halal* pharmaceuticals mean to pharmaceutical products that contain ingredients permitted under the *Shariah* law<sup>5</sup> and *fatwa*<sup>6</sup> which:<sup>7</sup>

- 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*; and
- 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) or e) or any other items that have been decreed as non-*halal* and *najs* by *Shariah* law and *fatwa*.

## Method

In general, the qualitative method is used in this study. The process begins with the submission of research questions made in general, followed by the selection of study subjects or related topics. The next process is data collection related to the title of the study. After that, the results of data interpretation followed by existing or new theories or concepts can be determined. This process is repeated to refine the research questions so that the questions are clear and accurate can be determined. For the purpose of answering streamlined research questions, further data collection needs to be done. After that the theory or concept can be firmly established. The next process is the discovery or conclusion of the study findings. In producing this qualitative study, a methods of data collection and methods of data analysis have been used. This study uses content analysis method<sup>8</sup> as a method of data collection. Content analysis is one of the research techniques related to written texts study. To complete this study, researcher has analyses such as the Holy al-Quran, *Hadith*, books, thesis, dissertations, journal articles, conference papers, legal statutes, standards, guidelines, work procedure manuals, magazines, newspaper clippings, authoritative websites, meeting minutes, working papers, proposal papers, speech collections of documents related to the study. This qualitative data has been

4 Department of Standards Malaysia, MS 2424:2019 Halal Pharmaceuticals General Guidelines (First Revision), (Selangor: Department of Standards Malaysia, 2019). Page, 5.

5 Communication from Allah concerning the conduct of the *mukalla*f which consist of a demand (commandments and prohibitions) and option or an enactment. *Shariah* law is divided into two, namely Taklifi and Wad'i.

6 Legal opinion concerning Islamic law issued by competent Muslim scholar. In Malaysian context, *fatwa* means any religious decree related to the religion of Islam which is verified by an authority, which consists of competent scholars.

7 Department of Standards Malaysia, MS 2424:2019 Halal Pharmaceuticals General Guidelines (First Revision), Page, 2.

8 Ghazali Darusalam dan Sufean Hussin, *Metodologi Penyelidikan Dalam Pendidikan* (Penerbit Universiti Malaya 2018), 467.

analyzed narratively, the process of qualitative data analysis obtained through documents and be analyzed vertically from top to bottom, starting from viewing, organizing, filtering, selecting, classifying and encoding themes then selecting categories and get the content of the descriptive text in depth which is have been able to answer the research question. Method of data analysis for the content analysis method is easier to do. The researcher only needs the required data and written in the field notes. At the same time, researchers also need to provide specific codes for indexing purposes. The content in each document needs to be reviewed to see if it is appropriate and matched to the research questions.

### Halal Certification Procedure in Malaysia

Department of Islamic Development Malaysia (JAKIM) is the competent authority in Malaysia stipulated by law for *halal* certification and the governing body that monitors and enforces *halal* regulations in Malaysia. In term of halal certification for pharmaceutical products in Malaysia, the basic references for *halal* pharmaceutical products shall comply with Malaysia Standard MS2424:2019 *Halal* Pharmaceuticals-General Requirements, Pharmaceutical Inspection Co-operation Schemes (PICs), decision of the National *Fatwa* Council for Islamic Affairs or *Fatwa* decreed by the states and others acts, regulations, standards and related guidelines. Management responsibility for multinational category applicant shall established Internal *Halal* Committee with reference to the Malaysia Guidelines for *Halal* Assurance Management System 2011,<sup>9</sup> appoint the *Halal* Executive, appoint minimum of two Muslim workers and shall be permanent post, Malaysia citizen, competent on *halal* management system and work fulltime in the handling/processing of pharmaceutical section. Applicant also shall establish the *Halal* Assurance System (HAS) with reference to Guidelines for *Halal* Assurance System Malaysia.<sup>10</sup> For the purpose of *halal* certification for pharmaceutical products, the applicants or manufacturers shall ensure that the product has been registered and has received the approval letter or registered products from the National Regulatory Pharmaceutical Agency (NPRA) Ministry of Health Malaysia.<sup>11</sup>

The following list of required documents and relevant certificates also need to be submitted either online or in-person:

- i. Company profile;
- ii. Company / business registration;
- iii. Name and description of product/menu for certification;
- iv. MAL Number/NPRA
- v. Ingredients used;

9 Department of Islamic Development Malaysia, *Guidelines for Halal Assurance Management System Malaysia* (Department of Islamic Development Malaysia 2011), 1-12; See also, Zulfakar Ramlee Saad, 'Prosecuting Shariah Offences in Malaysia: Evidentiary Issues' (2019) 4 *Petita: Jurnal Kajian Ilmu Hukum dan Syariah*; Siti Maimunah Binti Mohd Rijal and Rukiah Muhammad Ali, 'Efektivitas Pelaksanaan Sanksi Talak Di Luar Mahkamah Rendah Syariah' (2018) 3 *Petita: Jurnal Kajian Ilmu Hukum dan Syariah*.as well as the SCEA 1997, do provide general guidelines on criminal prosecution. However, there are still provisions that need to be improved. The question also arises as to how far forensic evidence can be used in proving these offences. The role of experts will also be studied and also using technology as a part of evidences. This paper will focus on the question of evidential requirements in prosecuting Shariah offences in the Syariah court in Malaysia. Undoubtedly, in realising this intention, it should not only be burdened on the shoulders of the prosecuting officers alone but the role to be played by lawyers, academics and judges will certainly have great impact in solving and improving these shortcomings. Abstrak: Masalah utama dalam penelitian ini adalah apakah prinsip-prinsip dasar bukti yang digariskan dalam Islam dan Sharia Court Evidence (Federal Territories

10 Department of Islamic Development Malaysia, *Manual Procedure for Malaysia Halal Certification* (Third Revi, Department of Islamic Development Malaysia 2014), 34.

11 *ibid.*

- vi. Name and address of manufacturer/ingredient supplier;
- vii. *Halal* status for ingredients with the halal certificate or product specification for critical ingredients (if relevant);
- viii. Type of packaging material;
- ix. Manufacturing process and procedure;
- x. Other documents such as ISO, GHP, GMP, TQM, etc. (If any); and
- xi. Location map of premise/factory.

Condition of Malaysia *halal* certification, the applicant or manufacturer shall:<sup>12</sup>

- i. register with the Companies Commission of Malaysia (SSM)/ Malaysia Co-Operative Societies Commission/ other government agencies;
- ii. hold a business license from the local authorities/testimonial from government agency;
- iii. in full operation before an application is made;
- iv. produce and/ or handle only halal products and in compliance with the specified *halal* standard;
- v. ensure sources for ingredients are *halal* and choose suppliers who supply *halal* materials or have obtained recognized *halal* certificate;
- vi. apply for all types of products/ menu which are produced by the factory/ premise; and
- vii. applications for repackaging must be accompanied with recognized *halal* certificate for the said products.

### Halal Certification Procedure in Indonesia

On the 25<sup>th</sup> October 2014, the House of Representatives in Indonesia passed the Bill of Halal Product Guarantee Law (Act no.33). The Bill of *Halal* Product Guarantee (*Undang-Undang Jaminan Produk Halal-UU JPH*), ordinarily known as the “*Halal* Law”. Upholding the constitutional mandate is the main reason behind the enactment of this new law which declared that the state is stimulated to provide the guarantees of its resident to perform their religious belief and worship. The scope of this Act is limited to food and beverages, pharmaceutical, cosmetic and leather goods exports with extremely strict provisions. Starting from October 2019 the **National Body of Halal Assurance (BPJPH)** will be the highest authority to issue *halal* certificates. Besides, MUI, as one of the highest authorities on Islamic affairs in Indonesia, will be in charge of issuing the *halal fatwa* and setting up the *halal* compliance standard. There are two major authorities under MUI —The Food, Drug and Cosmetics Assessment Agency (LPPOM), and MUI Fatwa Committee. Both of them are in charge of the *halal* audit, assessment and declaration.

During the transition period, the implementation of *halal* certification in Indonesia was implemented according to the same procedures. In term of *halal* certification to the pharmaceutical products. The assurance of *halal* products is done through LPPOM MUI certification using evaluation guidance of *Halal* Assurance System HAS 23000. The HAS 23000 is a requirement document for certification issued by LPPOM MUI. This HAS 23000 must be consistently implemented by food, drugs or pharmaceuticals and cosmetics product processor in order to get halal certificate. *Halal* Assurance System (HAS) is introduced by *Lembaga Pengkajian Pangan dan Obat-obatan Kosmetika Majelis Ulama Indonesia* (LPPOM MUI) since 2005, as a system to assure the *halalness* of product during validity of MUI *Halal* Certification. In order to support company to understand and implement the system. *Halal* Assurance System is an integrated part of *halal* certification process. *Halal* document certification requirements through the HAS document are as

12     *ibid*, 15.

follows:<sup>13</sup>

- i. Previous *Halal* Certificate
- ii. HAS Manual
- iii. HAS Status or HAS Certificate
- iv. Flow process chart of *halal* certified products
- v. Statement of pork free facility
- vi. Address list of all production facility
- vii. Evidence of *Halal* Policy dissemination
- viii. Evidence of HAS Internal Training execution
- ix. Evidence of HAS Internal Audit execution
- x. Business license

*Halal* Assurance System for a new company which has not obtained MUI *Halal* Certificate, HAS documents needed are:

- i. 1<sup>st</sup> HAS Document contains at least an official statement to submit Manual of HAS within 6 months after *halal* certificate is issued.
- ii. 2<sup>nd</sup> HAS Document contains at least *Halal* Policy, *halal* management organization, and scope of HAS implementation.

For company which has already had *halal* certificate but it HAS implementation has not been audited, then HAS documents needed are:

- i. 1<sup>st</sup> HAS Document contains at least *Halal* Policy, *halal* management organization, and scope of HAS implementation.
- ii. 2<sup>nd</sup> HAS Document contains standard Manual of HAS which consists of:
  - a) Company Profile
  - b) Document Control
  - c) Objective
  - d) Scope
  - e) *Halal* Policy
  - f) *Halal* Guidelines
  - g) *Halal* Management Organization
  - h) Standard Operating Procedures (SOPs)
  - i) Technical References
  - j) Administration System
  - k) Documentation System
  - l) Socialization Program
  - m) Training Program
  - n) Internal and External Communication System
  - o) Internal Audit System
  - p) Corrective Action System
  - q) Management Review System

For company whose HAS has been audited and is going to renew its *halal* certificate then HAS documents needed are:

- i. 1<sup>st</sup> HAS Document contains HAS implementation report on recent condition or revised HAS Manual or statement letter mentioning the company has got at least B grade or copy of HAS certificate.

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13 <sup>13</sup> 'Https://E-Lppommui.Org/New/', accessed on 26 Mac 2020.

- ii. 2<sup>nd</sup> HAS Document is not needed.

### **General Islamic Principles for Determination of *Halal* Pharmaceutical Products**

#### *The Islamic Principles Pertaining to Halal and Haram*

The first principle established by Islam is that the things which Allah has created and the benefits derived from them are essentially and hence are permissible. Nothing is *haram* except what is prohibited by a sound and explicit *nas* from Allah. The Islamic scholars have derived this principle of the natural usability and permissibility of things from the authoritative sources. Based on that basis in term of *halal* certification for the pharmaceutical products, all materials used in manufacturing and laboratory are halal compliant. The purchase, handling and sourcing of chemicals, reagents, apparatus, equipment and other items required for sampling and testing shall not be made from any source that is decreed as non-halal by *Shariah* law and *fatwa*.<sup>14</sup>

#### *Darurah*

Based on the Islamic principle “Necessities overrule prohibitions,” many Muslim scholars allowed patients to use medicines from non-*halal* sources provided that the medicine is prescribed by a reliable physician, that human life is at risk, and that no alternative medicine is available. *Darurah* or the state of absolute necessity, according to the terminology of Islamic law, is a condition that might cause harm to oneself or property which according to the Islamic law cannot be neglected and left to destruction and damage.<sup>15</sup> *Darurah* can be defined as unavoidable incident or emergency. In an emergency, it has its own set of rules. In a verse of Allah SWT says: “...when He has explained to you what is forbidden, except when you are under the compulsion of necessity.” (Q.S. Al-An’am 6:119). On the other hand, after mentioning his unlawful corpse of Allah s.w.t. says: “However, whoever is compelled to eat any of these because of absolute necessity, without willful disobedience or transgressing due limits in the amount taken it is no sin for him. Indeed, Allah is Most Forgiving, Most Merciful.” (Q.S. Al-Baqarah 2:173).

Accordingly, in the context of pharmaceutical products, the application of this *darurah* principle still applies to the factors of pharmaceutical products which are still in the critical category in terms of their use and not many alternatives in terms of their content.

#### *Fatwa*

Currently, each country has its own *fatwa* institution, whether as a government body, or under the tutelage of government, or outside of government jurisdiction. Moreover, there are also non-government bodies or *fiqh* academies that concentrate on the research of Islamic laws. For some countries, *fatwas* are issued by an official appointed *Mufti*, while those countries in absentia of an ordained *Mufti*, the authority of issuing *fatwas* is vested in certain Islamic bodies or organization.<sup>16</sup>

In Malaysia the *fatwa* committee is not directly involved in the *halal* certification process, but will convene if there is an issue in *halal* certification or to obtain Islamic *Shariah* decree, *halal* certification verification and decision will only be done by the Malaysian *Halal* Certification Panel (MHCP) consisting of *shariah* and technical experts and related government agencies or authorities.<sup>17</sup>

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14 Department of Standards Malaysia, MS 2424:2019 Halal Pharmaceuticals General Guidelines (First Revision), Page, 1-19.

15 Department of Islamic Development Malaysia, *Tafsir Ar-Rahman Interpretation of the Meaning of the Quran* (Department of Islamic Development Malaysia 2007), 49.

16 Department of Islamic Development Malaysia, Monograf Al-Ifta (First Edition), (Putrajaya: Department of Islamic Development Malaysia, 2010). Page, 12-13.

17 Department of Islamic Development Malaysia, *Manual Procedure for Malaysia Halal Certification* (n 10), 60.

While in the context of Indonesia *halal* certification, fatwa is an element in determining the *halal* of a product. Other than that, *halal* guidelines are established based on *fatwa* which is established through a collective decision within the MUI *Fatwa* Committee which is consisting of experts in the fields of *Shariah*, Islamic *da'wah*, *Ulumul Qur'an*, *Ulumul Hadith*, etc. The MUI *Fatwa* Committee is directly involved in the *halal* certification process of decision making based on the result of examination by LPPOM-MUI.<sup>18</sup>

### **Analysis of the Islamic Principles Criteria for Determination of Halal Pharmaceutical Products**

Based on the research conducted, there are several important criteria in the implementation of *halal* certification for pharmaceutical products, because the implementation of *halal* certification for pharmaceutical products is different from non-pharmaceutical products due to the use of critical ingredients and complicated in terms of production process. Therefore, a determination of the criteria is required in assisting the implementation of *halal* certification for pharmaceutical products. Other than general Islamic principles, *darurah* and *fatwa* based on the analysis, the determination criteria for *halal* pharmaceutical products has been identified are as follows:

#### *The Principle of Pharmaceuticals Derived from Halal Substances*

The main sources of pharmaceutical are plants, animals, minerals, micro-organism, synthesis materials, natural chemical and Genetically Modified Organism (GMO)<sup>19</sup> that have been created by Allah on the earth, as a gift to its followers. All *halal* substances are required for medicinal use while impurities are banned for use as medicines such as porcine based materials and substances that are defective. This is clearly mentioned in many of the *hadith* of the Prophet Muhammad (PBUH), one of which is Abu Darda' the following *hadith*:<sup>20</sup> "*Allah has sent down both the disease and the cure, and He has appointed a cure for every disease, so treat yourselves medically, but use nothing unlawful.*" (HR. Abu Dawud).

All materials also must be clearly defined and be *halal*. This includes all starting materials, packaging materials, and any in-process lubricants or agents that may come in contact with the product. As with any GMP, adequate documentation and procedures must be in place. *Halal* pharmaceuticals specifically shall include API, API Starting Material, intermediate, excipient, process aid, solvent, seed, cell bank, cell culture, growth medium, adjuvant, stabilizer, preservative, buffer and packaging materials that comply with *halal* principles and shall be free from *najs*.<sup>21</sup>

#### *The Principle of Maslahah*

The concept of *maslahah* has been discussed at length by several jurists. However, the two most prominent of them, as cited in the literature, are Al-Ghazali and Al-Shatibi. The former is considered as the one who first gave the original formulation of the concept from its rudimentary form, whilst the latter developed and refined the concept. The concept of *daruriyyah*, *hajiyyah* and *tahsiniyyah* in the context of pharmaceuticals or medicines can be distributed into 3 categories:

- 18 Mabims Harmonisation of Halal Standards Strengthening the Halal Industry, (A Joint Publication of The Ministers of Religious Affairs of Brunei, Indonesia, Malaysia and Singapore (MABIMS), Supported by the Islamic Development Bank (IDB) 2017, 23.
- 19 Department of Standards Malaysia, MS 2424:2019 Halal Pharmaceuticals General Guidelines (First Revision), Page, 10-12 (n 14); Mohd. Hisyam Mohd. Kamal, 'Human Rights Perspectives On Issues In The Implementation Of Islamic Criminal Law In Malaysia' (2019) Volume 4 Petita : Jurnal Kajian Ilmu Hukum dan Syariah.
- 20 Abu Dawud, *Sunan Abi Dawud* (Dar al-Kutub al-'Ilmiyah 2005), 610.
- 21 Department of Standards Malaysia, MS 2424:2019 Halal Pharmaceuticals General Guidelines (First Revision), Page, 12 (n 14).

- a. Critical pharmaceutical in terms of its use (*daruriyyah*), that is Control Drug, which requires prescription from the medical doctor, its use is critical and failure to take it, may cause of death and harm, the use of ingredients in the production process is made up from *halal* and *haram* sources. for examples like Prescription Only Medicine (POM), Non-Prescription/Behind the Counter (BTC), Vaccines/Biopharmaceuticals and etc.
- b. Medium critical pharmaceutical in terms of its use (*hajiyyah*), namely Over the Counter (OTC) medicine, which are available in pharmacies and supermarkets without special restrictions, its use does not reach the stage of bringing harm and death in the category of *daruriyyah*, for example fever and cough medicine. when in terms of the use of raw materials in the production process, there are alternative materials rather than non *halal* sources.
- c. Non critical medicine in terms of its use (*tahsiniyyah*), for example such as traditional medicine and health supplements or nutraceutical where its use is only *tahsiniyyah*, not taking it will not cause harm or death, when in terms of materials, the ingredients do not involve active ingredients, and there is alternative or *halal* sources in terms of productions.

### *The Principles of Ihtiyath*

The word *Ihtiyath*, etymologically, is a form of *masdar* from *fi 'il khumasi* (verb consisting of five letters) *ihthatha* which means to maintain, obstruct, and be careful. The word *ihthatha* come from the form of *tsulatsi* (root word consisting of three letters) *al-hauth* which means (something that surrounds/surrounds something else).<sup>22</sup> There are several propositions used by the Islamic Scholars in strengthening the existence of *ihthiyath* as one of the principles in the stipulation of Islamic law. Al-Zarkasyi also asserted that Imam al-Shafi'i in his opinion prioritizes the *ihthiyath*, because it is closer to *Shariah* purpose or objective.<sup>23</sup>

### Forms of *ihthiyath* application in Islamic Law:

- a. Establish the law with a most strength opinion - *Ihtiyath* is used when there are doubts about the law of a problem. One form of *ihthiyath* application is to establish more certain laws, according to their legal will.
- b. *Tawaqquf* in establishing *hukum*/law - one form of *ihthiyath* in establishing Islamic law is *tawaqquf*. *Tawaqquf* is to refrain from choosing one of the two laws before it is clear which law is strong and practiced. Therefore, the form of *tawaqquf* is the right attitude for him to use until it is clear which law will be used.
- c. Not take it lightly in terms of things that *mubah*/permissible - Basically the case of doubtfulness is a thing that is changed and is not an unlawful thing, but it has the potential to bring someone down to a case that is forbidden. Therefore, the Prophet Muhammad gave instructions to stay away from things that doubtful as a form of *ihthiyath* agar do not fall to unlawful things.
- d. Free from *khilafiyah* - avoiding things that are disputed about the status of *haram* and doing things that are disputed about the status of mandatory.
- e. Leave *rukhsah* when it weak in law - means *rukhsah* which is disputed by *ulama* - with meaningful disputes - regarding its legal status, not *rukhsah* that has been agreed upon by law or disputes that are not so strong.
- f. Taking most heavier *hukum*/law - taking most severe laws is one of the most famous

22 al-Qamus al-Muhith Muhammad ibn Ya'qub al-Fairuzabadi, *Al-Qamus Al-Muhith* (Muassasah al-Risalah 1987), 856.

23 Badr al-Din al-Zarkasyi, *Al-Bahr Al-Muhith* (Dar al-Kutubi 1994).

forms of *ihtiyath* among Islamic scholars.<sup>24</sup>

*Halal* pharmaceutical products certification requirements are as stated by *Shariah* law and *fatwa* that are incorporated into *halal* standards and guidelines. The complexity of *halal* certification process for pharmaceutical products comprising *halalness*, safety, quality and efficacy is in accordance with the application of *ihtiyath* principles as outlined by Islamic scholars.

#### *The Principle of Istihalah Tammah*

The word *istihalah* is a derivative of the word, *yastihil*, a term that carries the same meaning as the basic word change or change in taboo and the nature of something, and one meaning, again something absurd or impossible. However, in the context of this discussion, the first meaning of change is applicable. In English it is referred to as exchange, transformation and mutation.<sup>25</sup> In the modern context, it refers to a change something unclean or illegal substance that occurs naturally ingested or by using an intermediate materials such as chemicals and etc.<sup>26</sup> From the above definition, it can be concluded that the term of *istihalah* refers to a change of one impure or an illicit substance from its original nature to another, either by nature or by the manufacture or *sina'i* of which the properties of the substance have changed altogether in terms of its name, nature and shape. It proposes a new material that is different from the previous one. Thus, conceptually, through the process of making a thing, something unclean or something illegal to eat or drink, when it is changed to something else in a new form, name, character and nature, it becomes a sacred substance and *halal*.

The concept of *istihalah* is generally accepted by all Islamic scholars as a process of purification of impure or illegal substances even though they differ in their views on certain aspects and methods of use. In general, this concept is based on the foundations of the main sources of *Shariah* according to the al-Quran and the *as-Sunnah*. In the al-Quran, for example in verse 66 of *surah an-Nahl* Allah Almighty says: “And verily in cattle (too) will ye find an instructive Sign. From what is within their bodies, between excretions and blood, We produce, for you drink, milk, pure and agreeable to those who drink it.” (Q.S. an-Nahl 16: 66).

By taking into account or consideration the Islamic scholars point of view in the use of the *Istihalah*, which is not to be seen as too open or too rigid, especially to determine *halal* pharmaceutical products, then the appropriate method proposed is the used of *Istihalah Tammah* or perfect transformation, which is the perfect method of practice. *Istihalah Tammah* includes three aspects of transformation such as, the transformation of physical characteristics; second, the transformation of chemical substances, and thirdly, the transformation of both physical and chemical changes.<sup>27</sup> Physical transformation includes odour, taste and colour, whilst chemical transformation is the change of chemical substances in the product. In the case of transformation of both physical and chemical characteristics, a substance undergoes complete changes and transformed into a new material.

24 Muhammad bin Umar bin Husein al-Razi, *Al-Mahshul Fi Ilm Al-Ushul* (Jamiah al-Imam 1980), 217.

25 Harith Sulaiman al-Faruqi, *Mu'jam Al-Qanuni Lebanon* (Mu'jam al-Qanuni Lebanon: Lebanese Studies 1991), 23.

26 Wahbah Al-Zuhaili, *Al-Fiqh Al-Islami Wa Adillatuh* (Dar Al-Fikr 1997), 100.

27 Mohammad Aizat Jamaludin, *Fiqh Istihalah: Integration of Science and Islamic Law* (Revelation and Science 2012), 118; See also, Khaled Abou El Fadl, Ahmad Atif Ahmad and Said Fares Hassan, *Routledge Handbook of Islamic Law* (2019); Olaf Köndgen, *The Codification of Islamic Criminal Law in the Sudan: Penal Codes and Supreme Court Case Law under Numayrī and Al-Bashīr* (Brill 2017); NJ Coulson, *A History of Islamic Law* (Routledge 2017).

## Conclusion

Malaysia and Indonesia pharmaceutical industry growth are expected to continue, According to Islamic law, one of the main tenets of *Shariah* is the preservation of life. For this reason, pharmaceutical is allowed to be consumed whether it is *halal* or not, provided that there are no other alternatives. Currently in Malaysia and Indonesia, *halal* certification scheme for pharmaceutical products is available. However, criteria for determining *halal* pharmaceutical products need to be established comprehensively because the production of such products is very complicated and always exposed to the use of non-*halal* substances. The development of *halal* pharmaceutical products certification must comply with the *halalness* (materials and manufacturers) and *Toyyiban* (safety, quality and efficacy). To determine the criteria for *halal* pharmaceutical products according to Islamic law, certain principles have been identified or recognize such as the principle of pharmaceuticals derived from *halal* substances (synthesis materials, natural materials, plants, animals, minerals, micro-organism, natural chemicals and Genetically Modified Organism (GMO)), principle of *Maslahah* (*Daruriyyah*, *Hajiyyah* and *Tahsiniyyah*), principles of *Ihtiyath* and the principle of *Istihalah Tammah*. With these criteria, it can help in providing guidance to the *halal* certification bodies such as JAKIM and BPJPH in the implementation of *halal* certification for pharmaceutical products in Malaysia and Indonesia. In addition, the pharmaceutical products for *halal* consideration should follow any legislation and requirement enforced by the legal or competent authority in Malaysia and Indonesia. Once approved, the applicant or manufacturer should adhere to the conditions for the usage of *halal* certification and logo. The *halal* certification can be suspended or revoked if there is any breach in *halal* requirement and/or failure to sustain compliance.

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