

## Halal Pharmaceuticals

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**Abstract:** Halal products are fast gaining worldwide recognition as a new benchmark for safety and quality assurance. Products with halal certification are confidently accepted by consumers especially Muslims as well as those of other religions. Undoubtedly, halal product industry has been an emerging industry in Malaysia and all over the world. Recognizing the new concept of halal industry presents an opportunity for manufacturers to make better strategies and innovations in producing their products toward halal certification. Today, halal products are not focused only on food but all products including pharmaceuticals. Since, most of Malaysian population are Muslims, the Malaysian Standard on halal pharmaceuticals has been launched to ensure that manufacturers comply with the standard to produce them. This study studies on the fatwa related to pharmaceuticals such as usage of drug, gelatine and alcohol in pharmaceutical products. Apart from that this study also looks into the Malaysian Standard of Halal Pharmaceutical-General Guidelines in 2010 and other policies and regulations which have been set by the government. The finding shows that there is an unresolved issue of Shari'ah for pharmaceutical products due to the different opinions of fuqaha'. However, there are also many policies and guidelines on halal pharmaceuticals in Malaysia which are good for Muslim consumers.

**Key words:** Halal, halal pharmaceuticals, shari'ah law, regulation, halal standard

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### INTRODUCTION

Malaysia is a country that has a majority Muslim population. In spite of their geographic and ethnic diversity, Muslims follow their beliefs and the religion of Islam. Halal is a very important and integral part of religious observance for all Muslims. Hence, halal constitutes a universal standard for a Muslim to live by.

By definition, halal foods are free from any component that Muslims are prohibited from consuming. According to the Quran, all good and clean foods are halal. In non-Arabic-speaking countries, the term is most commonly used in a narrower context of Muslim dietary laws only, especially when meat and poultry are concerned. However, it also refers to a number of other consumer and industry related products like pharmaceuticals, biological products and fertilizers (Halal Group Industries PLC 2011). Meanwhile, haram means something that is prohibited in Islam. Consequently, almost all foods of plant and animal origin are considered

halal except those that have been specifically prohibited by the Quran and the Sunnah (the life, actions and teachings of the Prophet Muhammad). Halal food can be processed by using the same equipment and utensils as regular food with a few exceptions or changes. Similar to halal food, halal pharmaceuticals are supposed to come from halal, clean and healthy sources because they are something which are eaten or consumed. According to the Quran verse:

O ye who believe! Eat of the good things where with we have provided you and render thanks to Allah if it (indeed) He whom ye worship (Al-Quran, 2: 172)

Accordingly, all pure and clean foods and pharmaceuticals are permitted for Muslim consumption except for the following categories: any products derived from or contaminated with carrion of dead animals; flowing or congealed blood; swine and all its by products; animals slaughtered not in the name of God; animals killed in a manner that prevents their blood from being fully

drained from their bodies; animals slaughtered in the name of other than God; intoxicants of all types including alcohols and drugs; carnivorous animals with fangs such as lions, dogs, wolves or tigers; birds with sharp claws (birds of prey) such as falcons, eagles, owls or vultures; land animals such as frogs and snakes (Rahman, 2001).

Several factors determine the halal or haram status of a particular foodstuff. This depends on its nature, how it is processed and how it is obtained. Then we also must look at the food ingredients, emphasising on flavouring, amino acid, oils and extracts in the medicine or the food that we eat directly, grub as an example and blended products. Food and drink that are poisonous or intoxicating are obviously haram even in small quantities because they are harmful to health.

There is a staggering multi-billion dollar industry which is currently untapped. Outside of herbal and organic health food supplements, a majority of pharmaceuticals and medicines are not halal-compliant (Halal Group Industries PLC 2011). Medicines containing alcohol would be considered Halal if there were no suitable alternatives available. It should be noted that only ethyl alcohol such as methylated spirits and ethanol, the alcohol found in alcoholic drinks are intoxicating and are therefore haram. Other forms of alcohol (such as sterile) are not intoxicating. These types of alcohol will not be found in any food or drink due to the fact that they are generally poisonous but it is a point worth bearing in mind when buying household goods containing these. Some medicines and supplements also use gelatine as part of their capsules. It is permissible to use these if the gelatine is halal unless stated otherwise. If the medicine comes without label and the sickness is critical, the medicine can be used only if there are no suitable alternatives.

As a way to control use of non-halal elements in food and pharmaceuticals, Malaysia Standard provides to the food manufacturers HACCP and GMP with guidance in product processing in order to satisfy Shari'ah requirements. In other words, the Malaysian Standard provides the general guidelines on production, preparation, handling and storage of halal products which have been gazetted by the government, including for pharmaceutical products. The issue of certification is central to the global acceptability of halal products (Talib *et al.*, 2008).

## DEFINITION OF PHARMACEUTICALS AND DRUGS

Pharmaceutical is related to making and selling drugs and medicines (Oxford Advanced Learner's Dictionary: 1088). The study of drugs is known as pharmacology (Ishaq, 1997). It is about the study of manner in which the

function of living tissues and organisms is modified by chemical substances (Ishaq, 1997). Pharmacology also related to study the effect of chemical agents on living process.

Drug is a word which comes with certain aspects and purposes. It is known as something negative, dangerous and should be avoided. The word 'dadah' is used only in Malaysia while in Germany, Spain and France, drug is known as *rauschmitter*, *estupefaciente* and *drogue*, respectively.

**Drug as medicine:** Generally, drug means any substance that people use to cause the exchange of function and/or structure of organism physiology. However for the medical purpose the use of the word *dadah* is not allowed but it is called as *ubat* (medicine) even though some of these substances for medical purposes are misused.

**Types of drugs:** There are four types of drugs:

- Stimulant
- Depressant
- Hallucinogen
- Narcotic (Opiate)

**Stimulant:** Stimulant is a chemical substance that stimulates the nerve system which stimulates the brain. It makes someone eager to speak and happy (high). In addition, it also makes someone to sleep less and feel more confident. Usually, those who take this drug are mostly students. If someone takes an overdose of stimulant they will lose consciousness or faint. Among stimulant drugs are:

- Natural: cocaine, caffeine, epinephrine (Adrenalin<sup>®</sup>) and ephedrine
- Synthetic: amphetamines (Benzedrine, Dexedrine, Methedrine) and phenmetrazine (Preludin)

**Depressant:** In medicine, this drug is used to treat insomnia patients. It causes drowsiness. Another effect of this drug is that it makes people feel intense happiness and excitement (euphoria). However, it intoxicates if taken excessively. Among depressant drugs are:

- Natural: *cucare*
- Synthetic: barbiturate, tranquilisers (Librium<sup>®</sup>, valium) and methaqualone (mandrax)

**Hallucinogen:** Hallucinogen is a drug or chemical substance that causes hallucination. Users of this drug see colours brighter than usual and hear music more intense and meaningful. Among hallucinogen drugs are:

- Natural: cannabis, peyote (Mescaline), hallucinogenic mushrooms (Psilocybin), morning glory seeds

- Synthetic: Lysergic Acid Diethyl amine (LSD), Diethyltryptamine (DET), Dimethyltryptamine (DMT), STP (Dom) and Phencyclidice

**Narcotic (opiate):** This type of drug is the most dangerous drug and known as opiate. There are a lot of abuses of these drugs. It is medically used to cure sickness and potentially a cause of addiction. Some narcotics like opium, heroin, morphine and codeine are obtained from poppy plants and available in the Middle Eastern and Asian countries. Meanwhile, methadone and pathidine are human-made synthetic narcotics. Among the narcotics are:

- Natural: opium (candu) heroin, morphine, cocaine
- Synthetic: pathidine (mepuidine demerol) methadone (dolophine)

Generally, all medicine is risky when used. However, according to scientific evaluations, the risk outweighs the benefit obtained from the health aspect (Rahman, 2001). Abuse of the medicine arises when the medicine is used for purposes other than treatment.

So, drugs for medical purposes are called medicine being a material used for treatment in order to relieve, nurse, cure or to prevent illness in human and to increase their hygienic level (Rahman, 2001). It can be used in many ways and forms. Not only can medicine be eaten or drank but it can also be used in many ways such as through the anus (suppository) vagina, injection, implanted under the skin or applied onto the skin as cream or ointment (Rahman, 2001).

Prophet Muhammad (PBUH) said that every disease has its antidote. Base on the hadith (Jabatan Mufti Brunei Darussalam. Al-Hadaf):

Each sickness has medicine and if it is obtained heal comes by Allah's will. (Hadith narrated by Muslim): "Some Bedouin said to the Messenger of Allah (peace be upon him) should we look for medicine? He said (peace be upon him): "yes look for medicine because Allah (SWT) has provide medicine for each sickness, except one sickness: old age" (Hadith narrated by Bukhari)

#### **THE HUKUM (ISLAMIC VERDICT) OF MEDICINAL USE OF DRUG**

There are various fatwas with regards to this issue as outlined in the following.

**Scholars:** There is no hukum in the Quran or Hadith which directly forbids or allows the use of drug. However, generally Islam prohibits its followers from doing something which can damage themselves.

Some scholars agree that the hukum of drug is the same with that of liquor which is forbidden to be used. They used the juristic reasoning by analogy (qiyas) using the verse in the Holy Quran (Al-Quran, 5: 90):

O ye who believe! Intoxicants and gambling, (dedication of) stones, and (divination by) arrows are an abomination, of Satan's handwork: eschew such (abomination) that ye may prosper

However, the four scholars Hanafi, Maliki, Shafie and Hanbali did not mention any hukum related to drug use because it did not exist during their period and only appeared circa 106 or 107 A.H. from the commencement of the Government of Tartar.

**Fatwa in Egypt:** According to a fatwa decided by the Mufti, Al-Diar, Al-Masriah and Al-Sabiq (former Mufti of Egypt) and Al-Syeikh Hasanin Makhluif in his book 'Fatwa Al-Syari'yah', page 184 said, drug is forbidden to be used, to be given to be sold and to be traded. It is also agreed by the Hanafi and Shafie school of jurisprudence and Al-Syeikh Al-Islam Ibn Taimiyah from the Hanbali mazhab.

**Fatwas in Malaysia:** The Council of Rulers in its 126th meeting held on 24 February 1983 approved the opinion of the Fatwa Committee, Majlis Kebangsaan Bagi Hal Ehwal Agama Islam (The National Council for Islamic Affairs), Malaysia on the drug problem and decided the following: "any misuse, including the abuse of drugs according to Shari'ah is forbidden and drugs can only be used for medical purposes approved by the Shari'ah". However, prior to its use an advice from experts like a doctor must be obtained and its use must be based on the dosage approved by the doctor. The use of drugs is permitted based on the following fiqh principles:

- Necessity knows no law
- If there is a conflict between two evils, the lesser evil is committed to avoid the bigger one

#### **ISSUES REGARDING THE USE OF GELATINE AND ALCOHOL IN PHARMACEUTICAL PRODUCTS**

To discuss on the gelatine issue, the researchers will define the meaning of gelatine and the issues related to it.

**What is gelatine?:** Now a days, there is an issue of some pharmaceutical products containing gelatine. Gelatine is a clear substance used for making jellies (Longman Group, 1991). It is derived from the collagen of tissues by boiling them in water. It swells up when put in cold water but dissolves in hot water (Ishaq, 1997). It has been used hypodermically as a haemostatic and to promote coagulation in certain cases of disorders (Ishaq, 1997).

It has been stated that gelatine does not collapse at extreme temperatures, either the lowest degrees 0°C or at 100°C. Gelatine consists of 84-90% original protein, 2% mineral and the balance is water. It does not have cholesterol, preservatives, Arabic gum or locus gum that consists of carbohydrate. Among its names are halal gelatine, bovine gelatine, gum base, emulsifier and E441.

In the industry of pharmaceuticals, gelatine is used to make soft gel capsules, tablets and serums and also used in injection. There are two types of gelatine:

- Type A: obtained from porcine animals or non-halal animals which are mainly pigs. This type of gelatine if processed and mixed with acid can produce a large amount and with good quality
- Type B: obtained from bones and skins of cows and buffaloes which are processed in a mixture with alkali or lime water
- Muslims should find other alternatives for halal sources of gelatine like Vegicaps Soft which comes from plant sources for drug capsules

**Gelatine issue:** Currently, Holista Colltech (Australia) Ltd. a biotechnology company owned by Malaysia is trying to develop a method to commercialise a process of extracting collagen from skin of tilapia as a halal source of gelatine.

According to the Chief Executive of Holista Colltech, Dato' Rajen M. (Bakar, 2011). "The fish is suitable to make gelatine, however because of that chemical bond is not as strong as the pig's chemical bond, so they have to make a research and development on that source. He said that their scientists are working hard to make the chemical bond of that gelatine to be as strong as pig gelatine chemical bond".

He also said that the global market of gelatine is AS\$ 2.2 billion with an average 400,000 tonnes of gelatine produced per year. From that sum, 46% is made of pig and only 0.7% is made of halal gelatine. So, Holista Colltech is now trying to find local investors to set up facilities for extracting the world's first halal collagen in Malaysia.

Besides that a study done by the Ministry of Science, Technology and Innovation showed that out of

15 samples of pharmaceutical products taken randomly, three are wrapped with gelatines which are tested positive for pig DNA. The DNA was tested by using a diagnosis kit, produced by a local multinational company in an effort to develop halal standard products in Malaysia through a pioneer project with the ministry.

According to the Minister in Prime Minister Department, Dato' Seri Jamil Khir Baharom, there are many manufacturers of health products which do not apply for halal certificate from JAKIM or JAIN and only 20 supplement product manufacturers and 14 traditional medicine manufacturers obtained halal certificate from JAKIM.

### **FATWA REGARDING THE USE OF GELATINE AND ALCOHOL IN PHARMACEUTICAL PRODUCTS**

There are various fatwas related to the use of gelatine and alcohol in pharmaceutical products.

**National Fatwa Committee of Malaysia:** The National Fatwa Committee in its 8th meeting in Kota Kinabalu, Sabah on 24 and 25 September 1984 discussed the issue of gelatine in medicines and decided as following (Malaysia Standard, 2010): "The use of gelatine in medicine currently is permissible because of emergency. If there is any halal element which can replace the use of gelatine then is forbidden to use gelatine in the medicine." The skin of pigs, cows and the bone of animals are the main elements to produce gelatine. According to the Encyclopaedia of Chemical Technology, (Second Edition, Volume 10, 1960) most of Type A gelatine (acid process) produced by the United States are made from pig skins. Meanwhile in Europe, the skins and the bones of cows are used to make the gelatine.

According to the majority of the scholars, the use of forbidden substances or mixing with the najis for medical purposes is prohibited. However, the use of medicine mixed with najis besides alcohol in emergency situations is permissible according to Ibnu Ruslan (Shafie Mazhab) in Sunan Abu Daud, based on the Hadith al-'Urmiyyin narrated by Imam Bukhari and Muslim where by Prophet Muhammad (PBUH) asked his companion to drink the urine of camel. It showed that generally, the urine is haram. However, it is permissible during emergency period.

"When He hath explained to you in detail what is forbidden to you" (Al-Quran, 6: 119)

**Fatwa of Brunei:** Based on the fatwa of The State of Brunei, it was discussed about the mixing of medicine with alcohol and gelatine as follows (Jabatan Mufti Brunei Darussalam. Al-Hadaf):

According to Ensiklopedia Malaysiana (5/77) and Encyclopaedia Britannica (G.165) gelatine is used widely in the food industry and as the foundation of gelatinous food like jelly. It also functions as sweetener and used in the making of ice cream.

A lecturer from the Faculty of Science, University of Brunei Darussalam said that originally gelatine comes from animals. However, Ensiklopedia Malaysiana states that plant gelatines are the same as animal gelatine in their function and they come from wheat gluten or other wheat (5/77). So, it can be said that gelatine also comes from plants.

If the gelatine comes from animals, then we must look at the condition of those animals. If it is halal like cow, we must ensure that it is slaughtered according to the Shari'ah Law. However if it comes from pig, automatically it is forbidden to be used and known as najis (unclean).

If the gelatine comes from haram sources such as pig, or it is not slaughtered animals according to Shari'ah Law, the product is forbidden and najis. If it is mixed in medicines, the medicine becomes najis and is forbidden to use.

Meanwhile, alcohol is a colourless liquid produced by two ways of processing. Firstly, it can be produced by fermentation, the main process to produce liquor and secondly by chemical substances which is a process to produce alcohol from petroleum.

The product produced by this process is known as ethanol or ethyl alcohol. In the medical field, alcohol is used as an antiseptic and solvent. Methanol which is known as methyl alcohol or wood alcohol is poisonous (Malaysiana: 1/277).

All scholars (Hanafi, Maliki, Shafie and Hanbali) agreed that alcohol that comes from liquor is najis because it intoxicates, according to the Quran verse:

“O ye who believe! Intoxicants and gambling, (dedication of) stones and (divination by) arrows are an abomination of Satan's handwork: eschew such (abomination) that ye may prosper” (Al-Quran, 5: 90)

In the hadith related by Abu Tsa'labah, he said:

“We are neighbours to some Ahl Kitab (Jews and Christians) who cook in their pots pork and drink alcohol in their cups, the Prophet (peace be upon him) said: “if you get other than theirs use them but if not wash them with water and eat and drink” (Hadith narrated by Abu Daud)

In that hadith, Prophet Muhammad (PBUH) asked them to use other cask besides the cask which had been

filled with liquor. However if there is no other cask to be found they have to wash the cask used to fill the liquor before using it. It is because liquor is najis which is najis mutawassitah.

According to the late Pehin Dato Dr Haji Ismail bin Umar Abdul Aziz (former Mufti of Brunei) treating diseases with the original liquor (najis) is forbidden unless it is mixed with other things (Fatwa Series 34/70). Ibnu Hajar said in the hadith:

“It is permissible to heal with dead bones and other impurities both pure and mixed ones except wine; it is not allowed to heal with the pure one but is allowed with the mixed one.”

### THE NATIONAL MEDICINE POLICY

Currently, it is estimated that 52 million people died in the year 1997 of which 40 million live in developed countries, caused by pneumonia, malaria and Tuberculosis (TB) (Rahman, 2001). According to the World Health Organization by improving the access to current interventions for the spread of diseases and others, >10.5 million people can be saved a year until 2015 (Rahman, 2001).

It has been reported that 2 billion people which is approximately one quarter of the world citizen do not have access to basic medicines (Rahman, 2001). Subsequently, every country has to serve basic medicines to their citizen. The medicine does not necessarily have to be expensive but should be adequate such as cheap affordable supplements like iron and folic acid which can decrease the death rate of pregnant women and babies from the lack of blood (anaemia) (Rahman, 2001).

The National Medicine Policy (DUK) is one of the commitments to achieve the goal and a guideline to act in ensuring all the medicines are of good quality, safe and effective. It is obtainable with lower price so that all people can afford to buy (Rahman, 2001).

**Contents of national medicine policy:** The policy consists of all the components including (Rahman, 2001):

- The legal, guidelines and rules
- The choice of medicines
- The storage and contribution of medicines
- The guarantee of quality of pharmaceutical products
- The rational use of the medicine
- The economic strategy regarding medicines
- Monitoring and evaluation of DUK
- Research
- Development of human resource
- The technical contribution among countries

**Role of National Medicine Policy (DUK):** The National Medicine Policy (DUK) is needed to ensure that all people get the exact medicine for their need. Some people do not know how much medicine they must take such as paracetamol. Paracetamol (p-Acetylamino-phenol, Acetaminophen) is an analgesic drug which is increasingly encountered in overdose cases (Ishaq, 1997). In such patients, it may have fatal consequences, as a result of massive liver damage several days after ingestion. Paracetamol overdose can be treated with drugs such as cysteamine (Ishaq, 1997). The plasma level of paracetamol can be determined by gas-liquid chromatography by its UV absorption spectrum following extraction and by its colourimetric reaction with nitrous acid to form a yellow coloured nitrophenol (the Glynn and Kendal Method) (Ishaq, 1997).

#### **MALAYSIAN STANDARD OF HALAL PHARMACEUTICAL-GENERAL GUIDELINES**

In this part, the researchers shall discuss the Malaysian Standard of Halal Pharmaceutical.

**Introduction:** In Malaysia to produce halal food, manufacturers must refer to the Malaysian Standard of Halal Food-Production, Preparing, Handling and Storage-General Guidelines. There is also a Malaysian Standard for pharmaceutical known as Halal Pharmaceutical-General Guidelines to produce halal pharmaceutical products. It is the most current Malaysian Standard introduced by the Department of Standards of Malaysia in 2010.

In this standard, the Technical Committee on Halal Food and Islamic Consumer Goods consists of representatives from the following organization (Malaysian Standard, 2010):

- Department of Agriculture Malaysia
- Department of Fisheries Malaysia
- Department of Development of Malaysia
- Department of Veterinary Services
- Federal Territory Mufti Office
- Federation of Malaysian Manufactures
- Federation of Marketing Authority
- Halal Industry Development Corporation Sdn. Bhd
- Institute of Islamic Understanding Malaysia
- Malaysian Agricultural Research and Development Institute
- Malaysian Association of Standards Users
- Ministry of Agriculture and Agro-based Industry
- Ministry of Domestic Trade and Consumer Affairs
- Ministry of Domestic Trade, Cooperative and Consumerism
- Ministry of Health Malaysia

- Ministry of International Trade and Industry
- Muslim Consumers' Association Malaysia
- Royal Customs of Malaysia
- SIRIM Berhad (Secretariat)
- SIRIM QAS International Sdn. Bhd (Chemical and consumer section)
- Universiti Kebangsaan Malaysia
- Universiti Putra Malaysia
- Universiti Teknologi MARA

The co-opted members are (Malaysian Standard, 2010):

- Department of Islamic Development Malaysia (Halal Hub Division)
- Malaysian Organization of Pharmaceutical Industries
- Ministry of Health Malaysia (National Pharmaceutical Control Bureau)
- Ministry of Health Malaysia (Pharmaceutical Services Division)
- Pharmaceutical Association of Malaysia
- Science University of Malaysia

The Halal Pharmaceutical-General Guidelines outlines the basic requirement for halal pharmaceuticals in Malaysia. This standard is referred for inspection by the Pharmaceutical Inspection Cooperation Scheme (PIC/S): guide to good manufacturing practice for medicinal products and Pharmaceutical Inspection Cooperation Scheme (PIC/S): guide to good manufacturing practice for medicinal products annexes (Malaysian Standard, 2010).

#### **The contents of the Malaysian Standard of Halal Pharmaceutical-General**

**Guidelines:** Among the contents of Malaysian Standard of Halal Pharmaceutical-General Guidelines are.

**Halal pharmaceutical:** Pharmaceuticals referred in this standard are pharmaceutical products in finished dosage forms and include both prescription medicinal products for human use like bio-pharmaceuticals, radio-pharmaceuticals, traditional medicines and investigational medicinal products which are registered with the Drug Control Authority, Ministry of Health Malaysia (Malaysian Standard, 2010).

Halal pharmaceuticals are products that contain ingredients permitted under the Shari'ah law and fulfil the following conditions (Malaysian Standard, 2010):

- Does not contain any parts or products or animals that are non-halal by Shari'ah Law or any parts or products of animals which are not slaughtered according to Shari'ah Law

- Does not contain najis according to Shari'ah Law
- Safe for consumption, non-poisonous, non-intoxicating or non-hazardous to health
- Not prepared, processed or manufactured using equipment contaminated with najis according to Shari'ah Law
- Does not contain any human parts or derivatives that are not permitted by Shari'ah Law
- During its preparation, processing, handling, packaging and distribution, the food is physically separated from any other food that does not meet the requirements stated in items a-e or any other things that have been decreed as najis by Shari'ah Law

Najis according to Shari'ah Law are (Malaysian Standard, 2010):

- Dogs, pigs their descendants and derivatives
- Halal pharmaceuticals that are contaminated with items which are non-halal
- Halal pharmaceuticals that come into direct contact with items that are non-halal
- Any liquid and objects discharged from the orifices of human beings or animals such as urine, blood, vomit, pus, placenta, excrement and sperm and ova of pigs and dogs except sperm and ova of other animals. (Milk, sperm and ova of human and animals, except dog and pig are not najis)
- Maitah or carrion or halal animals that are not slaughtered according to Shari'ah Law and Khamar and food or drink which contains or mixed with khamar

Basically for the medicine to be classified as permissible not only the resources used as medicine materials must be permissible, the material itself must be pure from filth according to Shari'ah Law and used for legal treatment purposes (Rahman, 2001):

Look for medicine but do not do that from haram (forbidden) (Hadith narrated by Bukhari)

Basically, alcohol is haram. The Prophet Muhammad (PBUH) said:

“Wine is a disease which will not reduce illness, because it itself is an illness” (Late Maulana Mahmood Ahmed Mirpuri, 1998)

Therefore, it is considered wrong to use it even as medicine. However in exceptional cases, it may be allowed if there is no other medication available or as a last resort

to save from death. Similarly, anything haram may be allowed as a last resort if for example you are certain that if you do not eat it, you will die. To make something halal or haram, the criteria stated in the Quran as in Surah Al-A'raaf says:

He allows them as lawful what is good (and pure) and prohibits them from what is bad (and impure) (Al-Quran 7:157)

Whatever has been made haram for us will have some harm and disadvantages and scientific research has confirmed this. Alcohol was forbidden in three stages. Firstly, in Surah Al-Baqarah:

“They ask thee concerning wine and gambling. Say: “In them is great sin and some profit for men but the sin is greater than the profit” (Al-Quran 2:219)”

Secondly in Surah An-Nisa:

O ye who believe! Approach not prayers with a mind befogged, until ye can understand all that ye say” (Al-Quran 4:43)

Thirdly in Surah Al-Maidah:

O ye who believe! Intoxicants and gambling, (dedication of) stones and (divination by) arrows are an abomination, of Satan's handwork: eschew such (abomination) that ye may prosper. Satan's plan is (but) to excite enmity and hatred between you with intoxicants and gambling and hinder you from the remembrance of Allah and from prayer: will ye not then abstain? (Al-Quran 5:90-91)

**Requirement for halal pharmaceutical:** Furthermore for the purpose of halal pharmaceuticals, some of the requirements shall be incorporated within Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products and Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products Annexes currently being enforced by the relevant competent authority (Malaysian Standard, 2010). Among the requirements are (Malaysian Standard, 2010):

- Halal assurance system
- It shall be appropriate for the manufacturing of halal pharmaceuticals and shall be ensured that

- The pharmaceuticals are designed and developed in ways that comply with the requirements of halal and Good Manufacturing Practice (GMP)
- The production and control operations are clearly specified and good manufacturing practice adopted
- The processing line be operated for halal pharmaceuticals only and in the case of converting the processing line which contained or contaminated with najis al-mughallazah to a halal production line then the ritual cleansing method, refer to Annex A by Shari'ah law shall be required

**Fundamentals for halal pharmaceutical in GMP:** The requirements described in the PIC/S GMP Guidelines and PIC/S Annexes are integral and shall be referred for Halal Pharmaceuticals. The main control points are the source of materials and utilities that come into contact with the products.

The requirements to Good Manufacturing Practice (GMP) for Halal pharmaceuticals are listed below (Malaysian Standard, 2010):

- All materials are clearly defined with evidence of complying with Shari'ah requirements
- All necessary facilities and resources for halal compliance are provided including availability of:
  - Appropriately qualified and trained personnel
  - Adequate premises, space and services
  - Dedicated equipment
  - Correct materials, containers and labels
  - Approved procedures and instructions
  - Dedicated storage and transport
- All records are made, manually and/or by recording instruments, during manufacture which shall demonstrate that all the steps required by the defined procedures and instructions are taken and that the quantity and quality of the product is as expected. Any significant deviations are fully recorded and investigated
- All records of manufacturing including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form
- The distribution of the products minimizes any risk to their halal integrity
- A system is available to recall any batch of product from sale or supply
- Any complaints about marketed products are examined and the causes of halal non-compliance investigated. The appropriate measures in respects of the non-compliance are taken and shall prevent recurrence

**Halal quality control:** Halal quality control is to ensure all materials used are halal compliant.

**Personnel and responsibility:**

- The organization shall ensure that there are sufficient qualified personnel available to establish and maintain a satisfactory halal assurance system
- The organization shall establish a committee which is led by a trained Muslim personnel around 2/3 Muslim quorum

**Training:** Training is provided for all the personnel on the halal principles.

**Sources:** They are some medicinal resources which are human resources, animal resources, plantation resources, land and water resources as follows (Rahman, 2001).

**Human resources:**

- It is forbidden to use except in emergency cases when there are no choice
- Medicinal resources from human resources usually involve certain components like hormone, serum, immunoglobulin which is taken from human bodies

**Land animals and water animals resources:**

- All land animals and water animals which can be eaten can be used as medicinal resources
- Medicinal resources from the land and water animals which are forbidden to be eaten are filth except in emergency case

**Plantation and microorganisms resources:**

- All plantation and microorganism on land and water is permissible except those which are poisonous and dangerous

**Land and water resources:**

- All water and land resources including its deposits (includes mineral materials) can be used except those which are poisonous and dangerous

**Synthetic resources:**

- Synthetic processing
- Medicinal resources produced with synthetic ways are permissible except those which are poisonous, dangerous and mixed with filthy materials

**Excipient resources:**

- Excipient is additional materials used to bulk up formulation of medicine for example starch, capsule skin, solvent, sugar, preserves and others

- Excipient materials are permissible if it does not contain filthy materials, forbidden, poisonous and dangerous
- No exception in the usage of those excipient materials

Other requirements like management aspects, premises, equipment, production and storage areas and quality control areas must be Shari'ah compliant and prevented from being contaminated with non-halal elements (Malaysian Standard, 2010).

#### **Halal certification and halal certification mark:**

- The halal certificate shall be issued by the competent authority in Malaysia, JAKIM
- Upon approval by the drug control authority in Malaysia, each halal pharmaceutical may be marked with the halal certification mark of the Islamic authority

#### **CONCLUSION**

As a conclusion, the use of medicine mixed with alcohol and gelatine carries the same hukum with treating diseases with najis during emergency cases which is permissible but with conditions as stated. There are many cases regarding the food and pharmaceutical products today. Many of the products have been produced because of the increasing population and decrease in the sources. The government should be aware of the offences made by the manufacturers, so that we can restrain irresponsible manufacturers from continuously producing the products illegally.

As pharmaceuticals are a highly regulated industry in most countries, healthcare marketers need to be aware of regulations in the countries where they sell the products. Health is the most important aspect that should be concerned. Consumption of bad products will have a bad impact to the body. People must be concerned with the medicine they take because wrong medicine can cause

fatality. Currently, there are many health and slimming products offered in the market. People should be careful because the product may not have the same effect to their body. Besides, some products allegedly can cause other health condition and some of them can cause fatality. Hence, health must start with taking a balanced and healthy diet.

The manufacturers must be aware of the material they use in their products to avoid any non-halal element which may give bad impact to the consumers. The Malaysian Standard of Halal Pharmaceutical is the most important document which should be followed to standardize the quality and the safety of halal pharmaceutical products and to ensure that the consumers take the right medicine without any doubt about its permissibility.

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