

CRITICAL PROBLEM IN HALALNESS OF PHARMCEUTICAL PREPARATIONS

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Abstract

Consuming halal consumer goods, especially food, drugs, and cosmetics, is compulsory for every muslim. It is a matter of fact, however, a lot of consumer goods produced by non moslem countries that do not consider the halalness of the ingredients used. Consequently, moslem consumers must be well informed and careful in selecting what they consume.

The haram items are basically differentiated into two groups: (i) haram without specific reason (pork and blood), and (ii) haram with specific reasons, either its effect (alcohol/khamr), handling, or slaughtering system (islamic/unislamic). The original haram items, espicially of pig origin, are relatively easy to identify using modern chemical analysis but it is not the case for its derivatives (glycerine and fatty acids). More importantly the haramness of halal animals but slaughtered by an unsilamic rule. The detail of some important derivatives commonly used in drugs and cosmetic preapartions are discussed.

With regards to the fact that chemical analysis can not fully guaranty in identifying the presence of haram ingredients used in consumer goods it is urgent for moslems to provide all of their necessaties in accordance with islamic syari'ah.

INTRODUCTION

Foods, drugs, and cosmetics are all essential daily human needs demanded by modern society. In line with the progress in science and technology, the diversity of consumer products is increasing year by year. Consequently, consumers often do not know the actual contents of what they consume in terms of its raw materials and processing.

On the other hand, from a muslim point of view, knowing the starting material and production processes of consumer items is important. This is because anything consumed by muslims must follow Islamic Law (syari'ah), i.e **must be halal** (lawful). This situation is increasingly critical since many consumer products are imported from places that do not take into account the restriction of halal preparation according to Islamic syari'ah.

Similar implications arise for drugs and cosmetics. Uncommonly discovered that common drug and cosmetic preparations available in the market are haram according to islamic law. For example, the presence of lard and pig gelatin added/used in drug and cosmetic preparations either intentionally processed or because of contamination.

Haram and halal items

According to the Prophet saying (hadits) the halal and haram items are clear as stated below:

“Halal is clear and haram is clear; in between these two are certain things that are subhat (suspected). Many people do not know whether those items are halal or haram. Whosoever leaves them, he is innocent toward his religion and his conscience. He is, therefore, safe. Anyone who gets involved in any of these suspected items, he may fall into the unlawful and the prohibition. This case is similar to the one who wishes to raise his animal to a restricted area he may step into it.

Indeed for every land there is a restricted area. Indeed the restriction of Allah is Haram”. (Bukhari-Muslim)

The haram items are explicitly stated in the Holy Quran in the following verses: Al-Baqarah verse 173 and Al-Maidah verse 90.

*“He hath only forbidden you **dead meat, and blood, and the flesh of swine, and that on which any other name hath been invoked besides that of Allah.** but if one is forced by necessity, without willful disobedience, nor transgressing due limits, - then is He guiltless. for Allah is Oft-forgiving Most Merciful.” (Al-Baqarah, 173)*

*“O ye who believe! **Khamr (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-Maidah, 90)*

Looking at the above Quranic verses and the saying of Prophet it can be understood that the haram items are very limited and the halal items are abundant. What we are supposed to discuss and to talk about today is to clarify the “subhat” (suspected) to make clear on the basis of the true islamic teaching (Quran and Sunnah) and leave them because the subhat is closer to haram.

Based on the above Quranic verses the haram item can be categorised into two groups, i.e; (i) *haram items without any specific explanation **blood and flesh of swine/pork***; and (ii) *haram with specific reason or explanation, for example **dead meat** (unslaughtered halal animal or slaughtered in unislamic way), and **khamr**, because of intoxicating effect when consumed. In addition, the haramness of khamr was clarified by Prophet Muhammad SAW in his saying “kullu musykirin khamrun wa kullu khomrin haram” (every intoxicant is khamr and every khamr is haram).*

Haram items in drugs

Some haram goods or their derivatives that might be found in medical preparations can be listed below.

1. **Insulin.** It is a matter of fact that pig insulin is similar to human insulin. It is, therefore, understandable that **pig insulin** was commonly employed in the past. Nowadays it is still used about 17% of the time, but human insulin 70%, and cow insulin 8%.
2. **Heparin.** This compound work as anti-coagulating agent to prevent blockin blood vessel. Heparin was commonly **obtained from pig** (Sodium heparin, known as Lovenox, Aventis Pharma Specialitis, French).
3. **Gelatin.** Gelatin is a protein derived from animal collagen (pig, lamb, cow. Gelatin from pig is more abundant and largely used for capsul, therefore moslems must be aware of this reality.
4. **Alcohol.** This item is still used in cough syrup, for examples, Vicks formula (10,5%), Benadryl, PT Pfizer, (5%), Wood, Kalbe farma (6%),and OBH Combi, Cambiphar (2%). The present of alcohol is actually not absolute. It can be eliminated without reducing its effectiveness as an active compound. It is the responsibility of moslem pharmacists to provide non alcoholic formulas in accordance with islamic Law. Fortunately, alcohol is easily identified by simple chemical analysis. In addition many non alcoholic formulas with identical indication are available.
5. Beside alcohol, some derivates of haram items are also used in medical preparations. For examples, gelatin capsuls, enzyme, magnesium stearate (as lubricant). Calcium carbonate and calcium phosphate may also been derived from pork bone or from halal animal but slaughtered under unislamic way.

Haram items in Cosmetics

Haram items employed in cosmetics can be classified based on their origin, i.e.,human, animal, and plant. In the case of cosmetic preparations, the problem commonly relates to the “najis” (impure) status of the ingredients causing invalidity of shalah (prayer). Some of them are listed below.

1. **Keratin**, a chemical obtained from human hair, employed as colouring agent for hair.
2. **Albumin**, derived from human serum, used as solvent to dissolve active ingredient in cosmetic preparation.
3. **Placenta extract.** This is prepared by extraction of human placenta under a particular procedure. The extract is believed to be the cosmetic prepraation of choice for anti-aging and skin care. It is reported that **320 tons** of placenta are used per year. It was previously imported from Cuba but recently from China.
4. **Hyaluronic acid**, a chemical obtained from the womb, is used for whitening and skin care cosmetics. These four cosmetic preaprations employ human tissues and organs, therefore, are recomended not to be used by moslem.
5. Consumer products classified as subhat obtained from animal are mentioned below
 - a. **Collagen**, a protein as connective tissue and animal skin (pig, lamb, and cow) used for anti-aging, lipstick, and sikin care preparations
 - b. **Elastin**, similar to collagen.
 - c. **Fat and its derivatives.** Animal fats are commonly used for lipstick perparations, while its derivatives (glycerol and fatty acid and further derivate) are widely used in skin care preparations, for example creams and lotions. The chemical analysis is difficult to identify the original sources of these derivates, whether animal (pig or cow) or plant of origin.

6. Alcohol. This chemical is widely used in cosmetics especially as solvent for perfumary and many active compounds in cosmetic preparations. As has been previously mentioned the problem of the use of alcohol for external usage is whether alcohol categorized as *najis* (impure) or not. There is a long and continuous dispute on this matter. On the one hand, a group of ulama believe alcohol is najis therefore any cosmetic preparation must be free from alcohol. On the other hand, many ulama believe that alcohol is not najis, thus, alcohol is allowed to be used as solvent in cosmetic preparation. One thing that must be quoted is that alcohol easily vaporizes at room temperature. It means that soon after application alcohol will evaporate nearly completely.

Some subhat item

The disputable current issues are the derivatives of the haram item especially pork or flesh of swine and alike. There is no doubt that any materials obtained from pig are haram, however, the questions arising about the status of their derivatives as a result of chemical processes.

From the discussion with some ulama can be concluded that most ulama believe the derivatives of haram item especially from pig of origin are haram and also najis. Even, any products contaminated or processed by use of enzymes obtained from pig are categorized as haram/najis. This conclusion has been applied to meningitis vaccine that was declared by Indonesian Board of Ulama (MUI) in 2009. Related to this thought, the following items must be seriously considered by ulama and muslim scientist in order to save muslim ummah from consuming haram products.

1. Lard

This fat obtained from pig usually mixed with other fat, either animal or plant of origin. Fortunately this item is easily identified by modern chemical analytical methods.

2. Glycerin and fatty acids (Fat first derivatives)

These two compounds are derived from fat which are widely used in cream preparation. If obtained from pig fat (lard) and from halal animal but slaughtered in unislamic rule these two items are najis. Consequently the creams employing these items are najis.

3. Soaps, Nitroglycerin, and Mg-stearate (Fat second derivatives)

These two second derivative of fat are commonly used in cosmetic and drugs. Soaps and Mg-stearate are second derivatives of fat when fatty acids are treated further with suitable reagents. Mg-stearate is largely employed in tablet production as lubricant, while nitroglycerin is second derivative obtained from glycerin employed as an important medicine for angina pectoris. The halalness of this item is depending upon the origin of glycerin.

4. Some inorganic elements such as Ca and P are nowadays derived from pig bone by a series of chemical processes. Calcium carbonate and Calcium phosphate derived from pig bone are now in market.

5. Vaccine (Meningitis vaccine) was obtained in a series of processes, where one of which involving porcine (pig enzyme), was declared by Indonesian Board of Ulama (MUI) as haram. Consequently, similar vaccine products are categorized haram.

6. One important point should be noted is that many materials derived from haram items as mentioned above (Ca-phosphate, nitroglycerin, Mg-stearate etc.) are generally not written on the label of the products.

Critical Problem

What is meant by critical problem is how we can guarantee that the consumer goods consumed by muslim is halal in accordance with syari'ah, particularly the items derived from haram materials that were not explicitly mentioned on label.

Different from usual quality control of pharmaceutical products (drug and cosmetic) which mostly based on the presence and the quantity of active compound that have been accurately standardized on the basis their chemical properties, decision on halal and haram is more complicated and critical. Beside identifying the material on the basis of its chemical properties, haramness must also be evaluated on the basis of the original source ingredients whether halal or haram. A pure glycerin, for example, can not be differentiated whether it was derived from cows, pig, lamb, or plant of origin. In other words, the absence of pork derivatives, as indicated by DNA-based technology, does not necessarily mean that the items were not pork derivatives. It is easily understood, the same can be applied for further derivatives such as nitro-glycerin, soap, and Mg-stearate.

Similar case happen for the haramness/halalness of meat derived from halal animal. For the time being, Chemical analytical method can not be applied to differentiate the chemical composition between meat derived from animal slaughtered and unslaughtered; or between halal animal slaughtered by resiting basmalah and without basmalah. In this case, no valid correlation between halal/haram and chemical composition of the items in question has not been published. The presence of lard, gelatin, and other part of flesh of swine, on the other hand, can be detected by use of modern chemical analysis, such as Fourier Transform Infrared Spectroscopy (FTIRS), Electronic Nose (E-Nose) technology, and DNA-base technology that will be shortly illustrated below. This is because lard, gelatin, and flesh of swine indicate a different chemical composition from that of other animals.

Chemical Analysis

The development of chemical analytical methods is considerably significant in identifying the haram item especially pork and its derivatives. Some important methods developed recently are the followings.

- Fourier Transform Infrared Spectroscopy (FTIRS).
- Electronic Nose (EiNose) technology
- DNA-base technology.

FTIR Spectroscopy was reported (Che Man and Mirghani) to give accurate and reliable results with a 3% detection limit, applicable for lard in chocolate, cakes, and biscuit samples. In addition this method is simple to perform and offer rapid result (2 minutes)

Electronic nose technology is based on the development of a chemistry of odour where each odour is related to the presence of a specific compound. The instrument comprises an array of electronic chemical sensors and an appropriate pattern recognition system, capable of recognizing a simple or complex odour. It was reported this method could be used for monitoring the presence of lard in food sample such as cooking oil. In addition, it could also be applied to identify adulterated oil by the characteristic 2-dimensional olfactory images called VapourPrint™.

E-nose method is an interesting alternative choice offering easier operation with reliable results that could be achieved within minutes. It is, therefore, useful for rapid identification of lard adulteration in relatively low concentration (1%).

DNA-based technology is an important approach for species identification. It is understandable because DNA is relatively stable during and after process of production. The method was reported to give excellent results for pig species and its derivative in samples, particularly lard and gelatin.

The DNA-based analytical method is considered the most reliable method for determining halal status of an ingredient derived from pork. As has been widely known, every species has its own specific character different from the other. However, this is difficult to apply in its derivatives, especially when further reactions occur. For examples, glycerol-mononitrate, magnesium stearate, sodium/

potassium stearate (soap). This difficulty apply for dead meat and animal meat slaughtered under unislamic way. To the best of my knowledge, there is no difference in chemical specification or composition between meat derived by Islamic and unislamic slaughtering system. Once again, the haram status of these consumer goods is immaterial in nature, nothing to do with chemistry but fully on the basis of belief (*iman*).

Given the fact that foods, drugs, and cosmetics are of chemical origin, regardless they are halal or haram, consequently these three categories of important consumer goods, can basically be identified by chemical analysis on the basis of their chemical specific characters.

It is important to note that analytical methods are mainly focused on qualitative rather than quantitative analysis. This is simply because haram status is very much determined by the “kind” of matter rather than the quantity. In this regard, qualitative analysis is more focus only consumer goods (foods, drugs, and cosmetics) containing or consisting of those clearly prescribed by Allah SWT in the Holy Quran and as stated by Rasulullah Muhammad SAW. On the other hand, quantitative analysis is primarily aimed to determine the limit of detection using available analytical methods. It means that unidentified haram item does not necessarily verify the absence of the item analysed.

Looking at the above items classified haram, it is clear that the haram items used for drugs and cosmetics are relatively simple compared to that of foods. However, it is important to quote that chemical analysis can not verify the chemical derivatives obtained from haram substances.

Considering the problems faced by analytical chemist in supporting data for verification of halal products, there are several points that should be emphasized.

Firstly, haram goods are generally mixed, intentionally or unintentionally, with other items having similar chemical properties, for example, lard is mixed with fat from plant of origin. Consequently, it raises difficulty in identifying the target compound.

Secondly, if the haram item is a contaminant that appears during the process, meaning the quantity is relatively little, the method used must be sensitive and selective. Thus, the negative result does not necessarily mean the absence of the haram compound/item analysed. Consequently, another more sensitive methods of verification must be performed.

Thirdly, chemical analysis based on chemical properties of the haram goods can not verify the haram items that are immaterial in nature, i.e., of haram status due to slaughtering system. It is, therefore, direct and continuous “on the spot” monitoring by government authority is essential. More importantly, moslem must become producers of what they need.

CONCLUSION

- Halal-haram issue is very important and essential to every moslem life. The halalness of consumer goods need to be evaluated.
- Most drugs and cosmetic preparation subject to contain non halal items, especially derivatives of haram materials. Consequently, moslem awareness on this matter is urgent.
- Chemical analysis plays an important role in verifying the presence of haram product but does not cover all of haram matters, especially those the haramness is due to slaughtering system and the derivatives of haram materials (pork).
- Continuous communication between ulama and scientists is urgently needed in discussing and determining the

halal-haram status of pharmaceutical products.

It is highly recommended to Moslems to provide their necessities (drugs and cosmetic) to insure the halalness of what they consume.

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