



Halal ***pages***

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INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
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HALAL INDUSTRY
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Halal pages

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TM INFO-MEDIA SDN BHD – PUBLISHER

Chief Executive Officer Nasaruddin bin Mohd Zaini
Head of Business Strategy & Marketing Jimmy Yong
Head of Sales Eric Chew

PRODUCTION TEAM

Joint Editorial Team

Assoc. Prof. Dr. Hamzah Mohd. Salleh
 Jamal Abdul Nasser Zainal Abidin
 Abdul Rahim Ahmad
 Ahmad Md Redzuan
 Asma Nasaruddin
 Mazidah Ramli
 Yusroyka Karim

Technical Support Designer

Concept and Design TM Info-Media Sdn Bhd (178079-D)

Ground Floor, Block E,
 Mines Waterfront Business Park,
 No. 3, Jalan Tasik,
 Mines Resort City, 43300 Seri Kembangan,
 Selangor.

Tel: 03-8949 8228

Fax: 03-8949 8338

Email: help@yellowpages.com.my
 www.yellowpages.com.my

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 Lot 17-22 & 17-23, Jalan Satu,
 Bersatu Industrial Park,
 Cheras Jaya,
 43200 Cheras,
 Selangor

ADVERTISING OFFICES

Kuala Lumpur	Tel: 03-8949 8228	Fax: 03-8949 8338
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Halal Issues In Pharmaceutical Products

Urgent Need to Have Modern and Efficient Production of Pharmaceuticals and Biopharmaceuticals

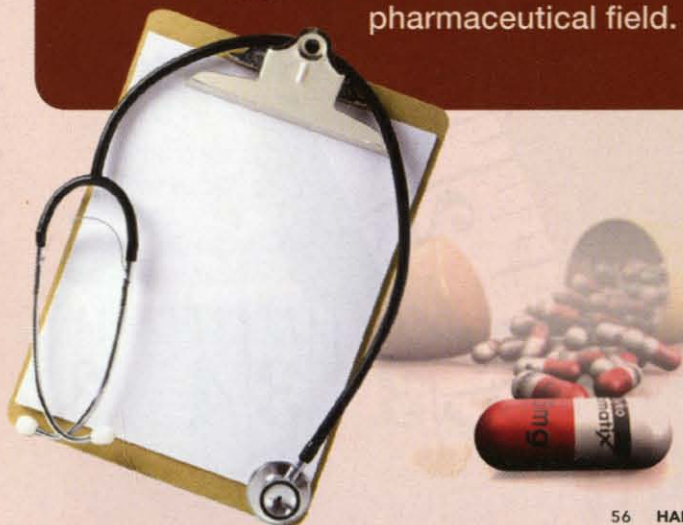


Maizirwan Mel and Hamzah Mohd. Salleh - maizirwan@ium.edu.my

Introduction


Muslims now make about one quarter of the world's population - there are altogether approximately 1.6 billion Muslims in the world spreading over all the continents especially in Asia and Africa, as well as sizable representation in Europe and North America. Despite this, 'Halal Issues in Pharmaceutical Products' is still being considered as a minor issue in the production of halal (permissible for Muslim) products in the pharmaceutical field.

Only recently, the demand for halal products, in particular food, is on the rise following the growing awareness amongst Muslims all over the world in relation to questionable or doubtful status of ingredients such as gelatin, emulsifiers and rennet in food products. In addition, the halal and haram status of such products are also dependent on the process compatible with the Islamic rules and regulations. Similarly, the concept of halal and haram applies to pharmaceutical products as well.



Halal Issues and Challenges

In general, ingredients involved in pharmaceutical production can be sub-divided as (a) process materials (materials utilized in the production process, in R&D laboratory and manufacturing); (b) pharmaceutical excipients (inactive ingredients component included in the final pharmaceutical formulation); (c) active pharmaceutical ingredients, API (any substance or



mixture of substances that is the active ingredient of the drug, intended to cause pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body); and (d) analytical reagent {chemical substances that contain sufficient purity that can detect any chemical substances for chemical analysis}. All active pharmaceutical ingredients (API) and excipients should be tested for safety, efficacy, quality, and hygiene before selecting for usage in the production of pharmaceuticals. The materials present in the final pharmaceutical product require verification that they are non-hazardous (not poisonous or toxic) before they are made available to consumers. The remainder of this essay touches on some of the common ingredients used in the pharmaceutical industry.

One of the long-standing issues regarding pharmaceuticals and biopharmaceuticals affecting Muslim consumers is the use of gelatin in many of these products. Gelatin is a protein which is normally obtained from two major sources: porcine (mostly from the skin and lately from the bone as well) and bovine (cow bone and hide). There is an urgent need to have modern and efficient production plants to supply halal gelatin suitable for the food and pharmaceutical industries.

Opportunity for a very good return of investment in such manufacturing plant is certain and could drive the industry now and in the future because (a) it is a religious obligation for Muslims to consume halal pharmaceuticals and biopharmaceuticals whereas many of these

products marketed nowadays are not halal or with questionable status - and this will spur demand for genuine halal products; (b) the growth in Muslim population; (c) the rising income among Muslim consumers created more demands and purchasing power for quality and halal

pharmaceuticals; and (d) the effort to satisfy the demand of halal pharmaceuticals for Muslim consumers and society at large is fard kifayah {an obligation if performed by some Muslims (a sufficient number), absolves all others of their responsibility}.

Beside gelatin, there are other excipients that may become an issue for Muslim consumers because lack of information/explanation. These excipients include dyes, flavors, binders, emollients, fillers, lubricants, preservatives, and many more classifications. It is not intended here to list all of the ingredients found in pharmaceutical products but some of the most common used pharmaceutical excipients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, silicon dioxide, corn starch, croscarmellose sodium and shellac.

Another pharmaceutical ingredient that always brings concern to Muslims is alcohol, more appropriately ethanol or ethyl alcohol. Ethanol is one of the mostly used liquid that serves as 'stabilizer' for a liquid form of medicine and also as a solvent in extraction process for pharmaceutical products. Alcohol compounds {hydroxyl (-OH) containing functional group} are generally allowed with the conditions that it is not derived from khamr (intoxicating alcoholic beverage or liquor) production and the quantity of ethanol (ethyl alcohol) in the final halal product (food or pharmaceuticals) is very small trace and that it will not

NO.	ITEM	REMARKS
1	lactose monohydrate	Mostly sourced from cow's milk. No issue. Halal
2	microcrystalline cellulose	manufactured from controlled chemical hydrolysis from plant materials. No issue. Halal
3	corn starch	From plant source. edible food substance and essentially nontoxic No issue. Halal
4	magnesium stearate	A magnesium salt of stearic acid fat. Normally from pig or non-Shariah slaughtered bovine source. vegetable source also possible. Used as lubricant in capsule or tablet preparation. halal and haram status depends on the source. Mushbooh (doubtful) if source is not mentioned.
5	silicon dioxide	Transparent, tasteless, powder that is practically insoluble in water. Main component of beach sand. Used as an absorbent and flow agent in supplements. May hinder digestion or uptake of other nutrients and deplete HCl. Chitosan (from exoskeleton of crustacean) is an alternative.
6	Shellac	A resin from the lac insect (a tropical insect) that consists of a complex organic polymeric molecule(s). Used as pharmaceutical tablet coating. Mushbooh (doubtful) or haram for some.
7	Gelatin	Sourced mainly from porcine and bovine. also could come from marine source. Halal if from marine or bovine source that has been Islamically slaughtered. Haram if sourced from pig. Mushbooh (doubtful) if source is not mentioned.
8	Croscarmellose sodium	From plant source. An internally cross-linked sodium carboxymethylcellulose. Used as a disintegrant in pharmaceutical formulations. No issue. Halal





intoxicate – current tolerable amount of 0.01% in the final product for halal certificate in Malaysia.

In pharmaceutical production there should not be any components that are not halal or doubtful according to the Shariah law, be it in large or small quantities that could jeopardize the halal consideration of the pharmaceutical. In addition, the processing area and all the processes should be free from any contamination from najis (filth) and microorganisms. The pharmaceutical products for halal consideration should follow legislation and requirement enforced by the legal and verified authority. In Malaysia for example, these competent authorities include the Halal Industry Development Corporation (HDC) and State Islamic Religious Department/ Council. Competent certifying

authorities will examine all materials and detail processes used in the production of the pharmaceuticals. Once approved, the manufacturer should adhere to the conditions for the usage of the halal certification and logo. The halal status can be suspended or revoked if there is any breach in halal requirement and/or failure to submit regular annual report.

Halal Issues in Biopharmaceuticals

The 21st century is said to be the century for biotechnology. It can bring a lot of benefits but also raises a lot of concerns to many people, society and countries. Genetically modified organism (GMO) is one of the fruits of modern biotechnology. GMO is an outcome of a deliberate manipulation of the genetic material of an organism - bacteria, yeasts, fungi, plants and animals. Biotechnological techniques and processes, as well as the GMO provide new opportunity in the pharmaceutical industry – production of biopharmaceuticals.

At least two major concerns affect Muslim consumers with regard to biopharmaceutical products and the materials and processes used in the making of such products. The genes in any of the procedures and/or GMO in the production of biopharmaceuticals must come from halal sources. If these genes are from non-halal sources or doubtful

sources, the biopharmaceuticals will not be suitable for Muslim consumers. The vector and the host for the expression of proteins must be validated that they do not pose any threat of toxicity or pathogenic. In addition, ingredients used in the growth media and subsequent downstream processing should be safe and devoid of haram or doubtful materials. Proteins, monoclonal antibodies, hormones and enzymes are some examples of biopharmaceutical products.

Concluding Remarks

It is a challenge to educate and convince manufacturers and society that halal products – food and pharmaceuticals - are not merely only for Muslims. Halal food and pharmaceuticals are very clean, safe and quality products for all consumers since they are prepared following the Islamic guideline as well as other internationally recognized standards.

