HALAL-BASED CAPSULE FOR PHARMACEUTICAL PRODUCTS; A MASTER LIST, AVAILABILITY AND PRODUCT UTILIZATION REVIEW

BY

MUHAMMAD FARAHI ‘ARIF BIN TAJUL ARIFFIN

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International Islamic University Malaysia

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ABSTRACT

According to a global statistic on gelatine production, 46% represented by porcine-derived gelatine, while the other 29% and 23% are represented by bovine hide and bone, respectively. Both porcine and bovine have issues related to halal status. Furthermore, gelatine is a common ingredient in pharmaceutical industry, especially in capsule shell production. Thus, the study aims to produce a master list which consists of all pharmaceutical products in capsule dosage available in Malaysia, and to evaluate their availability and utilization in community pharmacy and hospital. Based on the master list, the highest capsule source is bovine (61.5%), followed by vegetable (33.5%), hypromellose (4.1%), fish (0.6%), plant origin (0.3%) and porcine (0.03%). In term of halal certification code, H4 has the highest percentage (35.1%), followed by H1 (28.1%), and H3 (25.3%). In community pharmacy, products with bovine capsule shell have the highest availability (79.8%). However, products with vegetable capsule shell (58.3%) represent the highest average monthly utilization. The effect of master list as an intervention in community pharmacy is statistically insignificant. Nevertheless, there are still changes could be observed on the pre and post-test. The study in hospitals shows the products with bovine capsule shell and H4 code have the highest availability and utilization. The comparison between hospitals shows non-statistically significant difference. Based on the study, it could be observed that the majority of capsule shell used in pharmaceutical products registered in Malaysia have halal certification. Furthermore, the demand of halal-certified capsule pharmaceutical products is high. Thus, the concern on the halal status of pharmaceutical products could be reduced. The master list could be a prototype in educating healthcare practitioners on halal pharmaceutical.

مخَّلص البحث

وفقًا للإحصاء العالمي حول إنتاج الجيلاتين ، فإن الجيلاتين المشتق من الخنازير يمثل 46٪ ، بينما يمثل المشتقات من البقر و العظام 29٪ و 23٪، على التوالي. كل المشتقات من الخنازير والبقر لديهم مشاكل تتعلق بوضع الحلال. اضف الى ذلك، فإن الجيلاتين عنصر شائع في صناعة المستحضرات الصيدلانية ، وخاصة في إنتاج غلاف الكبسولات. وبالتالي ، تهدف الدراسة إلى إنتاج قائمة رئيسية والتي تحتوي على كافة المنتجات الدوائية التي على شكل كبسولة و المتاحة في ماليزيا، وتقييم مدى توفرها واستهلاكها في صيدلية المجتمع والمستشفى. بناءً على القائمة الرئيسية ، فإن أعلى مصدر للجلاتين في الكبسولات هو الأبقار (61.5٪) ، تليها الخضار (33.5٪) ، الهيبوميلوز (1.4٪) ، الأسماك (0.6٪) ، جذر النبات (0.3٪)، والخنازير (0.03٪). و على حسب ترميز شهادة الحلال، فإن H4 لديه أعلى نسبة (35.1 ٪) ، يليه H1 (28.1 %)، ثم H3 (25.3%). في صيدلية المجتمع، تتمتع المنتجات التي تحتوي على غلاف كبسولة الأبقار بأعلى توافر (79.8٪). ومع ذلك ، فإن غلاف كبسولة الخضار يمثل أعلى معدل للإستهلاك الشهري (58.3٪). تأثير القائمة الرئيسية كتدخل في صيدلية المجتمع ليس له دلالة إحصائية. ومع ذلك ، لا تزال هناك تغييرات يمكن ملاحظتها على ما قبل وبعد الاختبار. أظهرت الدراسة في أن المنتجات التي تحتوي على غلاف كبسولة الأبقار ورمز H4 أعلى توافر واستخدام في المستشفيات. تشير المقارنة بين المستشفيات إلى عدم وجود اختلاف إحصائي كبير. بناءً على الدراسة ، يمكن ملاحظة أن غالبية غلاف الكبسولات المستخدمة في المنتجات الصيدلانية المسجلة في ماليزيا لديه شهادة الحلال. علاوة على ذلك ، فإن الطلب على المنتجات الصيدلانية المعتمدة على الكبسولات الحلال مرتفع. وبالتالي ، يمكن تقليل القلق على وضع الحلال للمنتجات الصيدلانية. يمكن أن تكون القائمة الرئيسية نموذجًا أوليًا في تعليم ممارسي الرعاية الصحية على المستحضرات الصيدلانية الحلال.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice).

……..……
Siti Hadijah binti Shamsudin
Supervisor

……..……
Wan Mohd Azizi b. Wan Sulaiman
Co-Supervisor

……..……
Roziatul Akmam binti Osman
Co-Supervisor

I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice).

……..……
Shazia Jamshed
Internal Examiner

……..……
Noorizan Abd. Aziz
External Examiner

This thesis was submitted to the Department of Pharmacy Practice and is accepted as a fulfilment of the requirement for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice).

……..……
Norny Syafinaz binti Ab Rahman
Head, Department of Pharmacy Practice

This thesis was submitted to the Kulliyyah of Pharmacy and is accepted as a fulfilment of the requirement for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice).

……..……..……
Che Suraya binti Mohd Zin
Dean, Kulliyyah of Pharmacy

DECLARATION

I hereby declare that this thesis is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Muhammad Farahi ‘Arif bin Tajul Ariffin

Signature …… Date ……..

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Signature Date

The thesis is dedicated to my parents, Tajul Ariffin b. Noordin and Nor 'Aini bt. Dan for their continuous support, my supervisor and co-supervisors for all the advices and guidance, my colleagues and companions for the positive environment. Without all of you, it is impossible for me to reach up until this level of life.

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LIST OF ABBREVIATIONS

API	active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical
BSE	Bovine Spongiform Encephalopathy
CAGR	Compound Annual Growth Rate
CC	Colour Code
CD	Cross-Dataset
CJD	Creutzfeldt-Jacob disease
CoA	certificate of analysis
F	Frequency
FHCB	Foreign Halal Certification Bodies
GMP	Good Manufacturing Practice
GRAS	generally recognized as safe
HATTM	Tuanku Mizan Military Hospital
HAS	Halal Quality Assurance
HCC	Halal Certification Code
HKL	Hospital Kuala Lumpur
HLRT	Head-Left-Right-Tail
HUSM	Hospital University Science Malaysia
HVE	Halal Verified Engine
IBM	International Business Machines
IPF	Idiopathic Pulmonary Fibrosis
IREC	IIUM Research Ethics Committee
JAKIM	Jabatan Kemajuan Islam Malaysia
MINDEF	Ministry of Defence
MOH	Ministry of Health
MOHE	Ministry of Higher Education
Min.	Minimum
Max.	Maximum
MREC	Medical Research Ethics Committee
N	Total Sample Size/Number of products
NPRA	National Pharmaceutical Regulatory Agency
NCE	New Chemical Entity
NMRR	National Medical Research Register
OIC	Organization of Islamic Conference
OSHA	Occupational Safety and Health Administration
OTC	Over-The-Counter
PE	Pharmacoepidemiology
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
SD	Standard Deviation
SEM	Standard Error of Mean
SME	Subject Matter Expert
SOC	Source of Capsule Shell
UMMC	Universiti Malaya Medical Centre
UKMMC	Universiti Kebangsaan Malaysia Medical Centre
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

Malaysia has emerged as a leading country in Halal pharmaceutical sector, with the launching and development of the first Halal Pharmaceutical standard in the world, MS2424:2012 Halal Pharmaceuticals General Guidelines. The standard has been developed by Department of Standard Malaysia together with other government agencies and pharmaceutical industry (Akasah, 2014). Until now, the approval for using Halal logo by JAKIM has only been given for cosmetics, traditional medicines, health supplements and Over-the-counter (OTC) products. These product categories provide the customer with freedom in selecting which brand of products they want to use, while the usage and consumption of these products are not during emergency (*dharuriyyat*) cases. It might be indicated for general well-beings, common or mild disease.

Prescribed medications are not allowed to have halal logo by JAKIM in Malaysia. According to Islamic law, there is a leniency *(rukhsah)* for Muslim to perform something which is originally forbidden, in an emergency case (Nor Izyani Hanafi & Munira Muhammad, 2016). For instance, the consumption of pig-based drug in an emergency case, which may bring to the death of the patient, is permissible. At the same time, there is no other alternative medicine suitable to replace that pig-based drug. The choice of pharmaceutical products in poison list is not a freedom for consumers. It must be based on doctor's recommendation (Buang, 2014) except for poison group C and D (Laws of Malaysia, 1989).

As a quarter of the human population on the earth are Muslims, which are expected to grow by 35% over the next 20 years, increasing from 1.6 billion to 2.2 billion by 2030, Halal Pharmaceuticals sector shows a huge opportunity in the industry, with the increasing in awareness and demands among Muslim's consumer on the Halal status of drugs. Even in markets with Muslims as minority, when ranked by Gross Domestic Product at Purchasing Price Parity, large or developed countries, namely, the USA, Russia, UK, France, and Germany, are ranked among the top ten economies with Muslim buying power (Norazmi & Lim, 2015).

Gelatine is one of the main issues when discussing on Halal pharmaceutical, apart from alcohol, stearate, and glycerine. The majority production of gelatine from porcine source (46% of the total global gelatine production) is clearly prohibited for Muslim consumption. Apart from porcine issue on gelatine, the usage of bovine source in the production of gelatine, which represent the second largest percentage after porcine, also give another issue regarding halal status, either the bovine was slaughtered properly according to *Syariah* Law, or not (Karim & Bhat, 2008). One of the main roles of gelatine in the pharmaceutical industry is in the production of capsule shell.

1.1 RESEARCH OBJECTIVES

i. To create a master list of gelatine-based pharmaceutical products in capsule dosage form registered in Malaysia with different sources of capsule shell and halal certifications.

ii. To study the gelatine-based pharmaceutical products in capsule dosage form in community pharmacy.

a. To determine the availability and utilization of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy.

b. To evaluate the effect of master list as an intervention to the utilization of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy.

iii. To determine the availability and utilization of halal gelatine-based pharmaceutical products in capsule dosage form for different types of hospitals.

1.2 RESEARCH QUESTIONS

i. What are the sources of capsule shell and halal certification status for pharmaceutical products in capsule dosage form which have been registered in Malaysia?

ii. What is the reality of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy?

a. How much is the availability and utilization of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy?

b. What is the effect of master list as an intervention to the utilization of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy?

iii. How much is the availability and utilization of halal gelatine-based pharmaceutical products in capsule dosage form in different types of hospital?

1.3 RESEARCH HYPOTHESIS

i. There is difference on the utilization of gelatine-based pharmaceutical products in capsule dosage form in community pharmacy, before and after the introduction of the master list.

ii. There is difference on the availability and utilization of gelatine-based pharmaceutical products in capsule dosage form, between different types of hospital.

1.4 EXPECTED OUTCOMES

Basically, there are a few expected outcomes from this research, which are really prominent and important, especially for *Muslim* community. Firstly, from the result of this research, we will get the percentage of halal gelatine-based pharmaceutical products in capsule dosage form available, compare to non halal gelatine-based pharmaceutical products in capsule dosage form.

Based on the result, we could get an overview on how much is the exposure of non halal gelatine towards population in Malaysia, specifically in pharmaceutical sector, with *Muslim* as majority in population. Furthermore, from the drug utilization review, we could observe the demand of halal gelatine-based pharmaceutical products in capsule dosage form among consumers, in comparison with non halal gelatine-based pharmaceutical products in capsule dosage form.

The demands of halal gelatine-based pharmaceutical products will help us to discover the awareness of pharmacists and consumers on halal gelatine. If the awareness is still low, appropriate intervention need to be conducted, to increase the awareness among consumers and pharmacists, which will bring to the increase in demand of halal gelatine-based pharmaceutical products. The result for the study at hospitals will help us in comparing the practice in different types of hospital. It reflects the awareness and of healthcare practitioners in different hospitals.

The master list that will be produced from this research, could be a basic guideline for pharmacists to provide and dispense proper and appropriate gelatine-based pharmaceutical products in capsule dosage form, according to the religion of the consumers. When the master list has been introduced as an intervention, we could observe the effectiveness of the master list in helping pharmacists.

Furthermore, this master list could be one of the supporting evidence on the proposal to establish halal pharmacopeia (Ali & Wace, 2014). Halal Pharmacopeia is a very important guideline, to ensure the quality of life for the patients, while respecting their religion. Apart from halal pharmacopeia, which is usually being utilizing in research and industrial sector, a halal pharmaceutical practice guideline could be developed, which is more convenient for usage among healthcare practitioners, especially pharmacists in both community and hospital settings.

Three research objectives have been worked on through 3 studies. The figure below shows the studies with their respective objective:

Figure 2.1 Studies with Their Own Respective Objectives