

## Implementation of Halal Logistics in Halal Pharmaceutical Industry: A Study on Halal Warehouse System in Pharmaniaga Lifescience

**Muhammad Syukri Mohd Ashmir Wong (Corresponding author)\*\***

E-mail: syukri@uitm.edu.my

**Zatul-Ilia Hussin\*\***

E-mail: zatulillia@gmail.com

**Shofiyyah Moidin\*\***

E-mail: shofiyyah@uitm.gov.my

\*\*Akademi Pengajian Islam Kontemporari, Universiti Teknologi MARA  
40450 Shah Alam, Selangor, Malaysia

### **Abstract**

*The halal industry has become one of the main economic markets for world market growth. The need for halal in many industry segments has sustained the halal ecosystem, including the halal supply chain of products and services. Aside from halal food and beverages, halal pharmaceuticals also have a high demand for halal products and are marketed by Muslims worldwide. With the delicate, unique, and complex characteristics and processes of halal pharmaceuticals, a particular industry must take part in all requirements and measures throughout its supply chain. Thus, this research emphasized the role of halal warehouses as part of the essential logistics facilities for storing halal pharmaceuticals. Many risks will arise regarding the status of halal pharmaceuticals if the products are kept, stored, and handled in a manner underlined by the competent authority. Hence, this research focuses on discovering and ascertaining the industry implementation of halal requirements in warehouse management. This qualitative case study research was based on the data collected through interviews with the informants from the Warehouse Department of Pharmaniaga Lifescience (PLS). The research results revealed the PLS warehouse process flow, their halal implementation in warehouse management, and their perception of the importance of halal warehouse practice for halal pharmaceutical products. This could offer significant insight to the manufacturers, patients, users, researchers, or academicians.*

**Keywords:** *Halal Logistics; Halal Pharmaceutical; Halal Warehouse; Halal Requirements*

### **Introduction**

Halal logistics is relatively a process managing the procurement, movement, and storage of materials, parts and finished product inventory, and information flow through the organization following the Shariah law simplified in the comprehensive Halal standards and requirements underlined by the competent authority (Tieman, 2013). All the requirements are compulsory for the halal logistics providers to comply in ensuring the consistency of halal compliance for the products and services throughout the manufacturer's supply chain.

One of the critical components of logistics is warehousing and its management system. Warehouse interchangeably known as a distribution center means a place or space developed for efficient and effective storage and handling of materials, goods, and products (Logistics Bureau, 2017). According to Faber, de Koster, & Smidts (2013), warehouse management covers all systematic planning, controlling, and monitoring processes to operate the storage activities to meet the consumer's

demand.

Pharmaceutical products could be hazardous for the consumer if they were not kept, stored, and delivered based adequately on standards and requirements. Based on Sykes (2018), some incidents, such as improper temperature control, neglecting the time and proper handling during storage. It could make some drugs ineffective, harmful, and possibly even life-threatening to the people who consume them for everything from preventing the disease. This issue could also affect the status of halal drugs, which probably can be dangerous and considered haram to be prescribed to consumers or patients.

Based on the Malaysian Investment Development Authority (MIDA), the global pharmaceutical industry revenue reached US\$1.3 trillion in 2020 while the industry is expected to grow to US\$1.7 trillion in 2025 (MIDA,2021). Muslim spend on pharmaceuticals was US\$100 billion in 2021 and is forecast to reach US\$129 billion by 2025 (State of the Global Islamic Economy Report, 2022). As of 2023, 248 halal-certified pharmaceutical companies and 3604 halal pharmaceutical products were produced and verified by JAKIM (JAKIM (a), n.d.)

According to Roberta Pinna (2015), pharmaceutical logistics is the process of attempting to place the right medicines and medical items according to the right quantities, the medicines are in the right conditions, at the right healthcare service drop points, at the right time, for the suitable patients or users and the right cost. This is in line with the 7R logistics principle<sup>1</sup> practice portrayed by many sources as the logistics principles towards customer satisfaction. Thus, this research focuses on one of the Halal-certified

pharmaceutical manufacturers in Malaysia, Pharmaniaga Lifescience (PLS), towards implementing halal requirements in the warehouse of halal pharmaceutical products in PLS.

## Literature Review

### Overview of the Halal Logistics Industry

Undoubtedly, the Halal logistics industry also has to be part of the ample opportunity for industry players as it is an industry that creates a connection and essential collaboration to most industries, especially production companies. Based on (Mu'ti sazali & Ligte, 2019), Malaysia is known as the country pioneering and introducing halal certification for logistics which had been recognized by other Islamic countries in Asia, the Middle East, and North Africa and became a major catalyst for logistics providers to create networks within the country. Halal logistics is an exciting business venture for the industry player as the global halal food market value is projected to reach US\$2.6 trillion by 2023, and MAB Kargo Sdn Bhd (MASkargo) is expected to tap into the market to achieve the national target of RM50 billion halal export by 2020 ("MASkargo launches halal logistics division | The Edge Markets," n.d.). These values show that the growth of business profit in logistics operations could also have a positive impact on the food market and other sectors, including halal pharmaceuticals.

According to (Wazirah, Shah, Muhammad, Mohamad, & Suzana Jaafar, 2016a), the emergence of businesses and industries encouraged organizations to cultivate logistics systems or usage of logistics service providers (LSP) or sometimes known as third-party logistics (3PL). The growth of industries such as food, beverages, pharmaceutical, personal care, and all goods boosted the development of

<sup>1</sup> 7R logistics principles: Right Time, Right Place, Right Condition, Right Quantity, Right Cost, Right Customer & Right Products

logistics systems as corporate strategy, cost, and service advantage.

The implementation of halal logistics can be based on five principles that were highlighted and established by (Tieman et al., 2013), which are (1) intended to create a global halal logistics system, (2) minimize hardship for the halal industry with the presence of good networks between halal logistics operators, (3) define cross-contamination between halal and haram and how to avoid it, (4) development of a complete halal value chain and supply chain, and benchmark with existing halal standards, (5) best practices and international standards. The establishment of five principles is crucial to ensure that halal integrity can be preserved in any process during the inbound and outbound of halal goods and products. Meanwhile, research made by (Bruil, 2010) underlined three basic principles of halal logistics, which are (1) avoiding cross-contamination, (2) avoiding mistakes and (3) ensuring that operations are consistent with the expectations of the Muslim consumer.

### **Halal Pharmaceuticals: Concept and Definition**

Pharmaceuticals can be defined as a process connected with the science, preparation, and production of medicines (Cambridge English Dictionary, n.d.). Pharmaceutical products are any material or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form that is subject to control by pharmaceutical legislation in the exporting state and the importing state (World Health Organization, 2007). Pharmaceuticals are commonly related to drugs or medicine. According to Ab Halim et al., (2014), a drug can be defined as any substance used to cause the exchange of function and/or structure of organism physiology.

Next, the definition of halal pharmaceuticals precisely explained in MS 2424:2019 Halal Pharmaceuticals: General Requirements (First Revision), which is the products that contain ingredients permitted under the Shariah law and fulfil the six (6) main halal conditions such as the pharmaceutical products a) 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, b) do not contain najis, c) safe for consumption, effectual for human use according to prescribed dosage of quality and hygiene, d) it shall not prepared, processed or manufactured using equipment contaminated with najis, e) it also do not contain any human parts or its derivatives that are forbidden by Shariah law; and f) during its overall process of preparation, processing, handling, packaging, storage and distribution, the halal pharmaceutical products are physically separated 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 najis by Shariah law.

Another research by Tushar Saha (2019), explained that halal pharmaceuticals mean drug products that are derived from a permissible source following the Shariah principle, i.e., animals, plants, an organic or inorganic substance that follows a method of preparation, manufacturing and extraction that follows the commendations of Islam. Furthermore, Mohezar, Zailani, & Tieman (2016) have centralized the definition of halal pharmaceuticals with the concept of halal itself. They also stated that the medicines consumed by the consumers not only must contain ingredients permitted under the Shariah, but the medication also needs to be hygienic, pure, clean, and quality, which corresponds with the Toyyiban concept (Mohezar et al., 2016).

Table 1 below summarizes the definition of halal pharmaceuticals.

Sources	Halal Pharmaceuticals Definition	The similarity of the Shariah Principle
1 Department of Standard Malaysia (2019)	The products that contain ingredients permitted under the Shariah law and fulfill the six (6) main halal conditions, such as pharmaceutical products.	Included
2 Tushar Saha (2019)	Halal pharmaceuticals mean drug products that are derived from a permissible source following the Shariah principle, i.e., animals, plants, an organic or inorganic substance that follows a method of preparation, manufacturing and extraction that follows the commendations of Islam.	Included
3 Mohezar, Zailani, & Tieman (2016)	The medicines consumed by the consumers must not only contain ingredients permitted under the Shariah, but also be hygienic, pure, clean, and of quality, which corresponds with the Toyiyban concept.	Included

Source: Author

### Pharmaceutical Logistics and Supply Chain

Based on Kapoor, Vyas and Dadarwal (2018), the pharmaceutical supply chain can be defined as a process that provides medicines or drugs in the right quantity, with the right quality, to the right place and customers, at the right time and with optimum cost to be consistent with health system's goals and also it should make benefits for its stockholders. Logistics for pharmaceutical products is much more critical and complex since the activities are highly sensitive, and the manufacturers shall have a high concern for quality and time-bound (Bigoniya, 2012). Pharmaceutical products need temperature-controlled storage and distribution under strict regulatory control. The pharmaceutical supply chain illustrated by Kapoor et al. (2018) consists of the chain that starts from the supplier to the brand and generic manufacturers, to the distributor and government to the hospital or clinic, and lastly to the retailers. Warehouse functions as a part of the pharmaceutical supply chain shall regulate proper temperature control proper, handling and segregation of raw materials and products.

### Halal Warehouse for Halal Pharmaceutical Industry: Standards and Requirements

The manufacturer who conducted its

warehouse for the halal pharmaceuticals or any other logistics providers was also subjected to JAKIM's general and specific guidelines in Manual Procedure for Malaysia Halal Certificate (Domestics) 2020 (MPPHM 2020). The specific requirement, such as in Procedure 18 (6)(k)(i-v) under specific requirements for halal logistics (warehousing), there are several conditions to be complied with by the halal warehouse operators. For example, the segregation of halal goods or products shall follow their category, such as wet and dried products, the storage temperature shall be well-regulated upon keeping the halal products, and the warehouse shall have proper and maintained pest control management. Other than that, the environment of the warehouse area also shall be kept clean with the regular cleaning and sanitation schedule produced by the company.

Malaysian Standard MS 2400-2:2019, Halal Supply Chain Management System Part 2: Warehousing - General Requirements (First Revision) is typically a bit similar to Part 1 and Part 3 for transportation and retailing. However, this standard is more focused on the warehouse organization or LSP to refer to ensure their Halal management system for the warehouse is well operated according to Halal legal requirements. The contents of this standard include the requirement related to Shariah, which the organizations need to comply with all Shariah

requirements and/or Shariah practices. It also outlined the management aspects and procedures in planning, leading, and organizing toward the development of the Halal logistics system (Shariff & Ahmad, 2019). Other content bound is the Halal Risk Management Plan, the general requirement for the premise, infrastructure, personnel and facilities, and the maintenance of the halal supply chain.

Guide to Good Manufacturing Practice for Medicinal Products Part II by PIC/S GMP also underlined the specific standard and requirements for the storage and distribution of pharmaceutical products. Clause 10.1 encompasses the procedure for the production warehouse to provide adequate facilities for the storage of all materials under controlled and maintained conditions, especially in temperature and humidity control, and it should be recorded. Besides that, the quarantined, rejected, returned, or recalled materials should have separated storage areas for their temporary storage until deciding on their future use.

Chapter 3 of Guidelines of Good Distribution Practice (GDP) 2018 regulated by the National Pharmaceutical Regulatory Agency (NPRA) embedded the requirements related to the premise for storage of pharmaceutical products. Based on the guidelines, there must be a proper, well-maintained, and adequate premise, tools and equipment to handle and distribute the pharmaceutical to protect from any contamination and distribution of products/cosmetics (Ramli, Lukmani, & Potri, 2018). The focus of this chapter is to stress the requirement for appropriate temperature limits for the storage area, cleanliness and sanitation of the storage premise, and strengthening of security for the pharmaceutical products as these conditions consider critical aspects in storing the medicine.

### **Halal Warehouse Process Flow System**

The basic flow of the warehouse involves six primary processes, which are receiving, put-away, storage, picking, packing and shipping (Sunol, 2019). Receiving is a crucial process where the warehouse personnel shall ensure the received products are right in quantity and condition. Put-away means the products received from receiving area are moved to the designated and suitable storage depending on the product's requirement. Picking means the process of picking specific products for specific orders and customers. This process is where various technologies will be used to optimize the operations in a warehouse. Packing also is important due to ensure the products are not damaged during movement and before arriving to the customers. Lastly, the shipping process where it starts with to dispatch of the goods from the warehouse to the customer (Sunol, 2019). Logically, these general processes can also be adopted in the pharmaceutical industry as most logistics processes use the same logistics concept and requirement.

Research from (Aida, Fakhrlnizam, Suzari, & Hazariah, 2017), had developed a conceptual air cargo halal warehouse process according to the results of the study. Based on the research, the process in the halal warehouse for importing and exporting products. Based on the process, it can be understood that the general halal warehouse process includes the documentation process where verification will be conducted on the halal status of the products based on the supporting documents, verification and checking of the cargo condition, and the dedicated storage area where only halal products are placed and stored in the area.

### **Methodology**

The qualitative method is used to develop this research. The data collected in this kind of method will be collected through the semi-structured interview via face-to-face

and email with the informants pertinent to this research. For this research, qualitative research is the most suitable as it used a qualitative case study method on the purposive semi-conducted interview with the PLS staff and personnel in the warehouse unit. There are targeted participants chosen in this research since the participants are the person in charge of the overall management system of the unit. The main purpose of using this method is to acquire in-depth

information and immense knowledge related to the implementation of the halal warehouse for the halal pharmaceutical industry that was applied by PLS.

There are targeted participants chosen in this research since the participants are the person in charge of the overall management system of the unit, as mentioned in Table 2 below:

Table 2. List of PLS Informants

No	Informants	Position
1	A	Head of Unit for Warehouses PLS
2	B	Warehouse Personnel

In this research, the email interview and face-to-face interview methods are used to collect data from the informants. Interviewing comprises the activity of asking questions and getting answers from participants in this research. Interviewing can be in a variety of forms, such as through individual, face-to-face interviews, and face-to-face group interviews. Sections in the interview questionnaire comprise questions related to the implementation of halal requirements in warehouse operations. This section can meet the research objective, which is to ascertain their implementation of the halal requirement.

According to this research, there are several data analysis methods used to analyze the interview transcripts for the result and findings. This includes content analysis, transcribing the interview, and thematic analysis. Content analysis is the most common qualitative data analysis method as it is used to analyze documented information in the form of texts, media, or even physical items and is based on the research questions (Bhatia, 2018).

In this research, the interview made with the head of the warehouse and warehouse personnel of PLS used the thematic analysis to facilitate the researcher to summarize the abstract form of data and create the related themes from the collected data. This considered a systematic approach in recognizing every research question and

objective which to ascertain the implementation of halal requirements in the warehouse of halal pharmaceutical products in Pharmaniaga Lifescience.

## Results and Discussion

### Implementation of Halal Requirement in Warehouse

In general, a Halal warehouse is an operation that complies with all acts, related regulations, halal requirements, Standard Operating Procedures (SOPs), authority circulation notices, and standards. This can be achieved with the uniformity between staff and standards applicable to the process. As stated before, PLS is one of the halal-certified pharmaceutical companies and operates its warehouse within the establishment for their halal manufactured products. An awareness of the current halal standards and regulations of all related leaders and personnel is important to make sure halal compliance is maintained all over the manufacturing process. According to PLS halal implementation, they complied with two main halal normative references, the MPPHM 2020 and Malaysian Standard: Halal Pharmaceutical – General Requirements (First Revision) (MS 2424:2019). This includes PLS warehouse compliance, especially in the specific clause regarding storage and distribution in

both standards. These had been declared from the semi-structured interview by both informants that they were aware of the MS 2424:2019 and performing the works following the standard.

### Halal Documentation

Halal documentation is considered the main warehouse activity for the checking and verification process. The incoming materials transported by the internal transport or suppliers are required to have the supporting documents to declare the status of the halal materials. The warehouse personnel shall play a vital role in performing the efficient halal document checking and verification process. This process also helps them in preserving the halal integrity of the end products manufactured by the halal-certified pharmaceutical company. PLS had underlined the halal documentation that they required during the receiving of the materials in the warehouse. Other than Purchasing Orders (PO), invoices, and Certificates of Analysis (COA), they will verify the materials according to the Approved Halal Supplier or Manufacturer list. This is to ensure all the materials received are tally with the certified suppliers and would not simply approve any uncertain materials on their halal status as specified:

*"It is to check the documentation, if it has COA, DO, Invoice, and check if it is from the approved supplier manufacturer."*

Informant A

Furthermore, PLS also required a declaration form by the suppliers to assert that the materials are not transported

together with porcine and liquor products. This shows that PLS is committed to ensuring that the materials are not contaminated or even having cross-contamination with the forbidden (haram) sources. Precautions on cross-contamination with non-halal elements are important and correspond to the information from (Mara et al., 2014). They explained that the storage process in a warehouse should have no mixing of halal and non-halal goods on one pallet/load carrier or racks and no mixing of halal and haram products in the same cold room. To highlight, both informants detailed the same information regarding the declaration form:

*"Yeah, we have. During the receiving, we also have one form, which the material needs to declare to ensure no porcine and liquor products in the same transporter."*

Informant A

*"Yes. Documents such as Purchase Order (PO), Liquor and Porcine declaration form."*

Informant B

Other than halal documentation specified by PLS Warehouse, they are also focused on the safety and quality of products in compliance with other mandatory and voluntary bases of standards and regulations. As a halal-certified pharmaceutical manufacturer, PLS compliance with Halal standards also shall be incorporated with mandatory standards, which is PIC/S GMP enforced by the relevant authority. The relevant authority includes JAKIM, NPRA, KPDNHEP, and others. The example of standards, as detailed by informant A, is in Table 3 below:

Table 3. List of PLS Compliance and Certifications

No.	Standards Name
1	Pharmaceutical Inspection Cooperation Scheme Guide to Good Manufacturing Practice for Medicinal Products (PIC/S GMP).
2	MS 2424:2019 Halal Pharmaceuticals – General Requirements (First Revision)
3	Guidelines on Good Distribution Practice (GDP) NPRA 2018

4	ISO 9001:2015 - Quality Management System
5	ISO 14001:2015 – Environmental Management System
6	OHSAS 18001:2007 – Occupational Health and Safety
7	EU Good Manufacturing Practice (GMP)

Source: PLS Warehouse Department

## Segregation of Halal Materials and Products

Besides the Halal Documentation checking and verification process, there is another key activity in the Halal warehouse process, which is segregation. In any halal warehouse provider, they need to make sure all halal products stored and handled by them must be separated from non-halal products. Halal products also must be segregated from any dangerous products, intoxicants, and unsafe to avoid possible cross-contamination in Halal perspectives.

These requirements had been precisely indicated in MS 2424:2019 clause 3.9 Halal Pharmaceuticals stated that halal pharmaceutical products shall be physically segregated from all pharmaceutical products that do not follow the halal requirements such as (1) animal parts must be halal and slaughtered according to Shariah Law, (2) must be not from najis according to Islamic law, (3) safe, fit for human consumption, (4) equipment use to prepared, process, packed, and manufactured must be dedicated for halal products and not contaminated with any things which consider najis in Islamic law, and lastly (5)

must be not from human parts and derivatives that are not allowed by Islamic law and fatwa.

PLS Warehouse only manufactured halal sterile pharmaceutical products. There are about 29 types of pharmaceutical products in total. According to the informants, PLS Warehouse only accepts halal materials stored in the warehouse. There are two types of materials commonly used, which are animal-based and synthetic-based. Most of the materials used in production, Active Pharmaceutical Ingredients (APIs), and excipients are synthetic based, which means it is a chemical synthesis material that replicates natural products. Synthetic-based materials are considered not critical compared to animal-based materials because they do not contain any ingredients that are from animal sources.

Thus, PLS makes sure all animal-based materials must be accompanied by a valid halal certificate, a local or foreign certificate that is recognized by JAKIM, while other materials can possess a halal certificate or acceptable supporting documents such as product datasheet. The example of supporting documents are in Table 4 below:

Table 4. List of Halal Supporting Documents

No.	Supporting Documents
1	Materials/Product Process Flow
2	Product Specifications
3	Halal Declaration
4	Material Safety Data Sheet (MSDS)
5	Certificate of Analysis (COA)
6	GMP Certificates
7	Aflatoxins Declaration
8	TSE/BSE Declaration <sup>2</sup>
9	Allergen Declaration

Source: PLS Halal Assurance Management System

<sup>2</sup> TSE: Transmissible Spongiform Encephalopathy  
BSE: Bovine Spongiform Encephalopathy



The informants declared that all incoming materials are halal, which does not need vast segregation between the materials and finished products. Another concern is the dangerous drug seclusion. This is also interrelated with the halal-toyyiban segregation requirement, which relates to the safety and quality of halal pharmaceutical products. This relates to the research from (Mara et al., 2014) and (Kamaruddin et al., 2012) in the literature review that clarified the explicit separations of halal products to the designated warehouse and the separation of rejected products for follow-up actions. Both separations are needed to safeguard the Halal-Tayyiban integrity of the pharmaceuticals at all costs.

In PLS Warehouse, there are separate rooms to store the dangerous drugs to keep away from the approved materials and finished products. An example of dangerous drugs here is the rejected batch of materials that are unsafe or deteriorate from the pharmaceutical perspective. This segregation is vital to ensure there is no contamination and to avoid the materials and finished products stored in the warehouse turning into unsafe drugs as well as the halal-toyyiban status also can be questioned as declared:

*"At this moment, all the materials are halal and focus on dangerous drugs. We have a separate room for the dangerous drugs."*

Informant A

The dangerous drugs are handled according to strict procedures and shall be monitored and recorded by authorized personnel. In PLS, the authorized personnel is the certified pharmacist recognized by NPRA. The management of rejected materials or products is based on the regulatory guidelines and company procedures, such as in PLS Production and Warehouse SOPs. This information

mentioned by the interviewee:

*"All materials are halal and in terms of segregation of dangerous drugs and put in the specific room with SOP in WH-005 (Storage of Materials and Finished Products in Warehouse) and Production SOP."*

Informant B

### **Warehouse Cleaning and Pest Control**

According to MPPHM 2020, the sanitation system, including cleaning and pest control, is compulsory to be conducted by any halal manufacturing plant. It is a standard stressed by the Halal authority, JAKIM, the general requirement in clause 17 (10 a-g). Principally, a halal manufacturing plant shall regulate an environment's cleaning schedule, pest control system, which needs to be conducted regularly, and sanitation of equipment. The halal manufacturing plant shall be covered from the preparation until the distribution area. Therefore, PLS Warehouse is considered part of their pharmaceutical manufacturing plant for the storage and distribution area. According to the interview result, PLS has an established cleaning schedule for the warehouse, mobile racking, battery reach truck, and cold room. The cleaning process is conducted by the contract cleaners hired by PLS and monitored by the warehouse personnel as stated:

*"Yes. I also need to ensure the cleaners follow the cleaning schedule provided."*

Informant B

The regular cleaning schedules are provided by PLS Warehouse according to the SOPs, and they also established the warehouse cleaning logbook for cleaning record purposes. The cleaning process is conducted daily, weekly, and monthly based on the areas and equipment available in the warehouse. It is declared by the

interviewee:

*"It is executed by the contract company cleaners, and they are all trained to clean the warehouse. We also have SOPs and a Logbook for the cleaning of a warehouse. Basically, we have a schedule based on daily, weekly and monthly."*

Informant A

The pest control system also had been developed and applied to all areas and compounds of the establishment. It is conducted every week on Monday in the warehouse. The pest control system is conducted by external agents as mentioned:

*"Pest control system is implemented by hired agents by PLS."*

Informant B

### **Sertu (Ritual Cleansing)**

Sertu, also known as ritual cleansing, is one of the critical aspects of the halal requirement for a halal manufacturing plant. According to MS 2424-2:2019, Sertu means a cleaning process to the things, goods, items, or any parts that are contaminated by najis mughallazah according to Shariah law. This process is important, and the company needs to ensure all the staff is well-trained in the awareness, knowledge, and practical process related to Sertu. Besides that, there are two basic conditions for Sertu: pure water and clean soil. The halal manufacturing plants are subjected to JAKIM guidelines of Sertu, specifically for the premises and production plants. The application of Sertu in PLS is based on the SOPs developed by the Halal Committee Members. They had undergone the Sertu process as part of the halal training in the company, as quoted:

*"I think we have the SOPs for the whole plant. And we also had undergone Sertu practice before this at the production area."*

Informant A

The Sertu process in PLS is based on the established Work Instructions under Supply Chain Management. Sertu shall be applied in the warehouse if there is contamination with impurity categorized as Najis mughallazah at any affected warehouse areas, equipment, machines, tools, items, and materials. This act must be under their concern as if it is not applied, the halal status of the materials and finished pharmaceutical products might be at stake. The wisdom of Sertu is to promote the act of truthful purification and preserve the cleanliness and quality of a product. Though halal products do not only mean all the materials used are halal, but the safety, hygiene, and wholesomeness of manufacturing tools and the environment are also shall be their priority.

### **Warehouse Control Mechanism**

In PLS Warehouse, there are security doors, automated gates, and an automated garage equipped in the warehouse. These are high levels of security systems to enhance the control mechanism for the warehouse. It is definitely to prevent any unauthorized person or animal from entering the warehouse. Any animals are prohibited from entering the manufacturing plant at all, while the visitors are only allowed to enter the warehouse with the warehouse personnel's permission and to be escorted by them. The visitors who have legal permission to enter the warehouse will need to give their details in the specific visitors' logbook for record purposes. This is to make sure PLS Warehouse can make information traceable if it is required. This was mentioned by the interviewee:

*"Everyone except PLS staff who want to enter the warehouse needs to use an access card and visitor logbook with permission of warehouse personnel."*

Informant B

### **Warehouse Temperature Control**

Halal or conventional pharmaceuticals' criticality is all about the temperature. The higher the temperature monitoring, the lower the chance of deteriorating the medicine. Fundamentally, the pharmaceutical manufacturer aims to produce a safe medicinal product to heal people. Thus, controlling the temperature of materials, processing, packaging, storing, and transporting the finished medicinal products are necessary to prevent any possibility of product damage or to turn them into dangerous drugs. Sterile products in PLS are concerned about temperature suitability according to their characteristics and specifications. For that reason, the PLS warehouse plays a vigorous role in maintaining the temperature for the incoming materials, storing them, handling them to the production area, packing the finished sterile products, and sending them to the internal transporter.

Both Halal and GMP conditions specified the requirement for proper temperature control at all possible processes for the pharmaceutical products to prevail the safety of the products when they arrive at the end consumer. If this process fails, a huge risk will occur, especially for public health issues. According to the semi-structured interview, PLS Warehouse is well-equipped with modern technology and facilities, which consist of three (3) main cold rooms with a different range of temperatures. The purpose of having all these cold rooms is to store the materials before providing them to the production area, to store the finished products, and to bulk-packing the finished products before

distributing them to the main Pharmaniaga logistics hub. The temperature control in the warehouse also is monitored by the warehouse personnel through the system analysis program (SAP) system, which helps to give an alarm or alert to the staff when there is a problem, or the temperature is out of specification (OOS), as mentioned before. This is according to the interviewee:

*"We use the system in normal times and during MCO. Another advantage is also our warehouse temperature control and humidity, which is quite crucial in the warehouse. Then our system uses a Real-time data logger. From that, we can check the temperature of the warehouse just at home. Even though the temperature is Out of Specifications (OOS), the system will send the alarm through the handphone or email."*

Informant A

The three (3) ranges of temperatures include 15°C to 25°C, 2°C to 8°C, and -15°C to -25°C and based on the products characteristics and storage specifications required as stated:

*"We have 3 ranges of temperature, from 15°C to 25°C, 2°C to 8°C, -15°C to -25°C."*

Informant A

Most PLS products are stored at 15°C to 25°C, such as Sodium Bicarbonate w/v Injection, Furosemide Injection, and Atropine Sulphate Injection. A product like Lidocaine Hydrochloride Injection is kept at 2°C to 8°C, and Rocuronium is stored at the coldest temperature of -15°C to -25°C. The temperature control storage must be executed and monitored by the warehouse personnel according to the PLS Warehouse SOP as mentioned:

“Yes. Based on PLS Warehouse WI W-019 (Operation of Temperature Controlled Store).”

Informant B

The PLS Warehouse practice is aligned with the research detailed in the literature review (Bigoniya, 2012) mentioned that pharmaceutical logistics is much more critical and complex due to the features of the products being highly sensitive and the manufacturers required to have a great concern to quality, temperature-controlled storage and time-bound under strict regulatory control. The safety and quality of pharmaceutical products are also part of the binding requirements for a halal-certified pharmaceutical. This is under the literature review quoted (SciSafe, 2019); the pharmaceutical storage is subjected to strict guidelines in which all drugs must remain within their endorsed temperature ranges or else fail to meet the temperature range even if it is different 2°C from the actual temperature, it will cause risk to the product safety and quality.

Overall, all these findings prove the implementation of halal logistics in the halal pharmaceutical industry conducted by PLS are well dedicated and along with the requirement set by the competent authorities. It is also able to secure the halal integrity of pharmaceutical products by implementing the halal logistics warehouse system.

## Conclusion

PLS was certified halal by JAKIM under Malaysian Standard MS 2424:2019 Halal Pharmaceuticals. All operations in PLS, including receiving, dispensing, filtration, packaging, and storing, comply with the standards and manual provided by the authorities. Generally, there are general and specific halal requirements established by the authority like JAKIM and NPRA for the pharmaceutical industry, as well as

the systematic SOPs built by the company. All levels of management have their roles in implementing the halal requirements throughout the process, including a warehouse in PLS. Thus, the objective was formulated to ascertain their implementation of halal requirements, specifically in the warehouse operations for the halal pharmaceutical products manufactured by PLS.

There is halal documentation specifically for the incoming materials and products, segregation, cleaning, pest control system, Sertu (ritual cleansing), warehouse control mechanism, and last but not least, temperature control. To conclude, all criteria were generated and complied with PLS Warehouse according to the SOPs, halal standards, and requirements. There are also additional sections that comprise the control point determined in the PLS Warehouse, and their overall assurance on the halal requirements has been conducted and implemented in the warehouse. These sections are also significant in ascertaining the related halal requirements in storing, handling, and packaging process that had been conducted in the PLS Warehouse. It is recommended to expand the area in this research. Future researchers are encouraged to explore the importance of halal warehouse practices for halal pharmaceutical products.

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