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A Qualitative Study on the Implementation of *Sertu* in Pharmaceutical Industry: Processes, Issues and Challenges

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Abstract

Recently, halal pharmaceutical is starting to get the place in the market and is well-accepted among Muslim and non-Muslim consumers. To be certified halal by JAKIM, emphasis is notonly on the origin of the ingredients, but also the manufacturing process whether it complieswith the requirements set by halal pharmaceutical standards. According to Malaysian Standard, MS2424 Halal Pharmaceuticals Guideline, *sertu* cleansing need to be conducted if contamination with severe *najs* (*naj mughallazah*) materials occurs. However, there have been very few studies conducted on halalpharmaceuticals especially on *sertu* cleansing in pharmaceutical industry. Hence, this exploratory qualitative study was conducted to provide insight into the way *sertu* process is carried out in the pharmaceutical industry, and to determine the importantenabling factors needed and the challenges faced in an effort to establish a halal-certified pharmaceutical industry. The data was collected through semi-structured in-depth interviews in two halal-certified pharmaceutical companies in Malaysia. The study used purposive sampling as information could only be obtained from specific target employees inhalal-certified pharmaceutical companies. The results of this study indicate that processes, people, training, records, and materials used for *sertu* are important enablingfactors needed for sertų implementation in pharmaceuticals companies. The study also has identified the effect of *sertu* implementation to Good Manufacturing Practices (GMP) status in pharmaceutical industry and the challenges faced by industry players along the *sertu* implementation process which inludes lack of awareness of *sertu* cleansing by the halal certified pharmaceutical industry players and Muslim consumers, issues with the standard and financial issues in implementing the *sertu*. A proposed conceptual framework was developed from the findings of the study.

Keywords: Halal pharmaceuticals, Halal medicines, Seru cleansing, Halal pharmaceutical industry, Good Manufacturing Practice(GMP)

Introduction

Malaysia has become a leading country among several other countries (e.g. Egypt, Singapore, Indonesia etc.) in incorporating halal value in pharmaceuticals and cosmetics productions (1).Halal pharmaceuticals provide a way for Muslim consumers to preserve their faith and belief even in health care practices (2) It should be free from haram constituents and tayyib, which means they have to be clean, pure and produced based on standard processes and procedures (3). Halal pharmaceuticals are produced based on the harmonization of Islamic religious law, GMP standards as well as the approved halal supplier and material list (4).

"Halal" is an Arabic term meaning permitted, and the opposite is "haram" meaning unlawful for a Muslim based on the Quran (5).The MS2424 requires a product to be approved by National Pharmaceutical

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Regulatory Agency which signify safety, quality, and efficacy and comply with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards first before it can be certified halal (6). The MS2424 Halal Pharmaceuticals General Guidelines defines halal pharmaceutical as a product that containing ingredients permitted by Islamic law and fulfilling the following conditions(7).

a) Any parts or products of animals used should be halal and slaughtered according to Shariah Law;
b) Free from *najs* according to Shariah Law;
c) Possess no harm to human health in accordance to prescribed dosage;
d) Are prepared, processed and manufactured using equipment that are free from *najs* according to Shariah Law;
e) Free from human parts or its derivatives that are not permitted by Shariah law; and
f) Halal pharmaceutical products should be physically separated during its preparation, processing, handling, packaging, storage and distribution from any other pharmaceutical products that do not fulfil the conditions stated in items a), b), c), d) or e) or any other items that have been decreed as non-halal and *najs* by Shariah law.

A halal product will lose its purity if contamination with non-halal substances occurs.The storage, equipment and handling facilities which have been contaminated with severe *najs* (contaminant of porcine and canine origin) need to be cleansed by *sertu* cleansing for purification using water mixed with clay(8). However, in pharmaceutical productions, the possibility of the products to be contaminated by the *sertu* clay need to be considered so that high-quality and safe pharmaceutical products can be produced. In addition, pharmaceutical productions also often involve with the use of sensitive equipment that require extra precautions during its cleaning and handling. The use of clay in *sertu* cleansing could cause scratch and damage to the equipment if the cleaning process is not conducted in an appropriate manner. Therefore, a standard operating procedure (SOP) for *sertu* that would comply with both GMP, and halal requirements should be developed by the organizations involved in order to implement *sertu* guidelines effectively.

Sertu (ritual cleansing), is a Malay term, defines as Islamic method of cleansing to eliminate*mughallazahnajs* (e.g. dogs, pigs, or their descendants) by washing contaminated surfaces with water mixed with soil (one time) followed by clean water (six times) (9, 10).*Sertu* cleansing is crucial to ensure toharah (purification) in Islam so that ibadah (worship) will be accepted (8).

According to MS2424 Halal Pharmaceuticals Guidelines, the general requirements of *sertu* cleansing include (7):

a) Seven times washing, one of which shall be water mixed with soil,
b) The first wash shall be to clear existence of *najs*, even if a few washes are needed. The water from the first cleaning shall not remain behind and the next wash shall be counted as the second wash.
c) The amount of soil used is just enough to sufficiently change the physical appearance of water from clear to turbid.
d) The usage of cleansing agent containing soil is permitted.

Sertu cleansing will not only remove the existence of *najs* from the view of religious faith, but also the negative energy from it. Contamination by *najs* may occur at any stage along the halal supply chain processeswhich involve the use of transport and containers, warehouse, surrounding areas and infrastructure (e.g. floors, loading bays, storage rooms) (11).

Traditionally, any fixed concentration of clay can be used for *sertu* cleansing. However, some modifications need to be conducted for industrial applications sinceimproper selection of clay can cause physical damages (e.g. rust, scratch, and blockage) on sensitive and expensive instruments as well as harmful to human (9). Corrosion can occur at the minimum level in

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the pH range of 6-12 of the clay, while rust can rapidly occur outside this range which would be fasten by very acidic or alkaline conditions(12). Smaller clay particle size will increase the clay's ability to absorb and remove impurities due to its large surface area. Clay also can regulate the flow of cleaning products on the target surfaces due to its impacts on the viscosity (9). Heavy metals contaminants of the clay (i.e. mercury, lead) must not exceed the allowable limit as they can accumulate in the body if they are ingested. The clay also shouldhave a low moisture content so that it could stand for a longer-term storage condition (9). Surface properties such as the chemical composition, phase composition, and roughness can affect cleansing ability of the soil on the glazed surface. Repeated soiling and cleaning showed accumulation of soil on surfaces with highest roughness (13).

Issues and Challenges in *Sertu* Implementation

Some pharmaceutical companies need to spend up to thousands of U.S. dollars per year to meet halal requirements stated in the guideline including replacement of any prohibited ingredient which has been identified during ingredient's information review and the facility audit (14). In addition, Halalstandards also need to be implemented parallel with other recognised international standards such as Hazard Analysis Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) to consistently produce medicinal products to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification (7, 15, 16). Lack of understanding in halal (permissible) and its association with tayyiban (wholesomeness), especially among the manufacturers, service providers and consumers could present threats to the success of halal productions. Lack of understanding of the halal procedures could contribute to a slow process and minimizes the number of halal certificate approval. (17, 18) Similar understanding and operational practice of handling halal products between all parties are important to maintain an intact halal integrity from upstream to downstream supply chain.(19). Hence, this study is conducted to understand the processes, issues, and challenges in implementing *sertu*according to the guidelines in the MS2424 Halal Pharmaceuticals Standard in halal-certified pharmaceuticals companies in Malaysia.

Materials and Methods

This was qualitative research since there was very few research done on the *sertu* cleansing. It is exploratory in nature and is very useful since not much is known about targeted phenomenon until now (20). The study used purposive sampling and took place in two pharmaceutical companies located in Selangor which are Company A and Company B withthe targeted employees who are knowledgeable about the *sertu* process to obtain a maximum insight for the case studied(21). Table 1 summarizes the participants' information.

Semi-structured in-depth interviews were conducted to obtain a rich and in-depth information about the experiences of the individuals. It can occur either with an individual or in group (22). A total of three individual interview sessions were conducted with the employees from Company A and a focus group interview was conducted with the employees from Company B. The interviews were guided by semi-structured interview protocol previously constructed based on literature reviews. Each interview session lasted between thirty minutes to one and half hour, at a time, by using combination of Malay and English language. Notes were taken during the interviews, and the interviews were recorded with the participants' permissions for later transcription (23). An extensive review on relevant literatures and previous studies retrieved from different databases were performed before and during data collectionto gain better understanding on the subject matter (24).

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Table 1: The participants' information for Company A and Company B

Company	Type of company	Position	Years in Industry
Company A	Halal-certified Pharmaceutical Company	Microbiologist in QC	3 years
Company A	Halal-certified Pharmaceutical Company	Halal Executive	8 years
Company A	Halal-certified Pharmaceutical Company	QC Technician	6 years
Company B	Halal-certified Pharmaceutical Company	Top Management Level	21 years
Company B	Halal-certified Pharmaceutical Company	Secretary for Halal Council	9 years (in halal)
Company B	Halal-certified Pharmaceutical Company	Senior Manager/ Shariah Advisor for Halal Council	12 years

Results and Discussion

In the study, the data was analysed inductively started with gathering all information related to the case including the transcripts, records, the investigator's own documents, and voice recorded interviews. The data was managed manually with the help of Microsoft Word rather than with the use of computer programmes (eg.ATLAS.ti, Nvivo) to eliminate the gap between the researcher and the data (25). Thematic analysis was conducted by using coding method (open coding and axial coding) to categorize the data that seems related to each other into categories/ theme (26).

Enabling Factor of *Sertu*

Five requirements as the enabling factors were formulated from the interview sessions: the processes, the people, the training, the records, and the materials used for *sertu*.

Processes

Sertu cleansing in Company A was conducted due to the history of using non-halal materials (e.g. raw materials, media) in production. It was carried out by 15 employees in the microbiology lab and 30-50 employees in the production line. The whole process was observed by Selangor Islamic Affairs Department (JAIS) staff and halal executive officer. It began with the investigation of the processes and machines that had been contaminated with non-halal materials and removal of all non-halal materials. The operations in the affected areas were stopped for a week to allow the *sertu* cleansing (two days) and environmental monitoring (five days) to be conducted (Figure 1).

First, washing of equipment was conducted with clay water which had been prepared earlier by JAIS followed by another six times of washing with clean running water (by spraying with clean water for sensitive equipment). The water was allowed to spread evenly over the surface of the equipment.The equipment was wiped immediately after each spray by using clean cloth to prevent any damage occurring. All lab coats were soaked in the clay water (first washing) followed by in the clean water (subsequent six washing). The tables were wiped by using clean clothes which had been soaked in the clay water (first washing) followed by another six times washing with clean water by using the new clean cloth. Cleaning as per Standard Operating Procedure (SOP) and environmental monitoring were conducted after the *sertu* cleansing has completed (after drying and assembling).

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Sertu cleansing in Company B was conducted for peace of mind since the company has been involved in manufacturing for quite a while where there is a possibility that contamination may have occurred during that time. The production process in Company B was stopped for a week to allow sertu cleansing (two days) and environmental monitoring (five days) to be conducted. The number of staff involveddepends on the number of equipment and the size of the affected areas. The clay water was prepared by halal executive and verified by shariah advisor of the company under JAIS's supervision. Before it was used for *sertu* process, the clay undergone sterilization by autoclaving. Microbial tests were conducted on the clay before and after sterilization to ensure the safe use of the clay. The employees learned on-the-spot on how to perform *sertu* by using three cleansing methods (washing, spraying and rinsing) on the actual day of the *sertu* process. The whole cleansing process was observed by officers from JAIS. The GMP cleaning and environmental monitoring were conducted after the cleansing process was completed. GMP cleaning also was conducted before the *sertu* cleansing. The company need to pass the environmental monitoring (e.g. swab test, settle plate) before the operation can be started.

People

Sertu process in Company A was led by the Head of Production and halal committee members and supported by JAIS. A briefingwas given by JAIS before the*sertu* process was conducted. The employees were divided earlier into groups and each group was guided by staff from JAIS. The company also was guided and advised by Halal Industry Development Corporation (HDC) during the implementation process. The shariah competent authorities (JAKIM, Selangor Islamic Religious Council (MAIS)

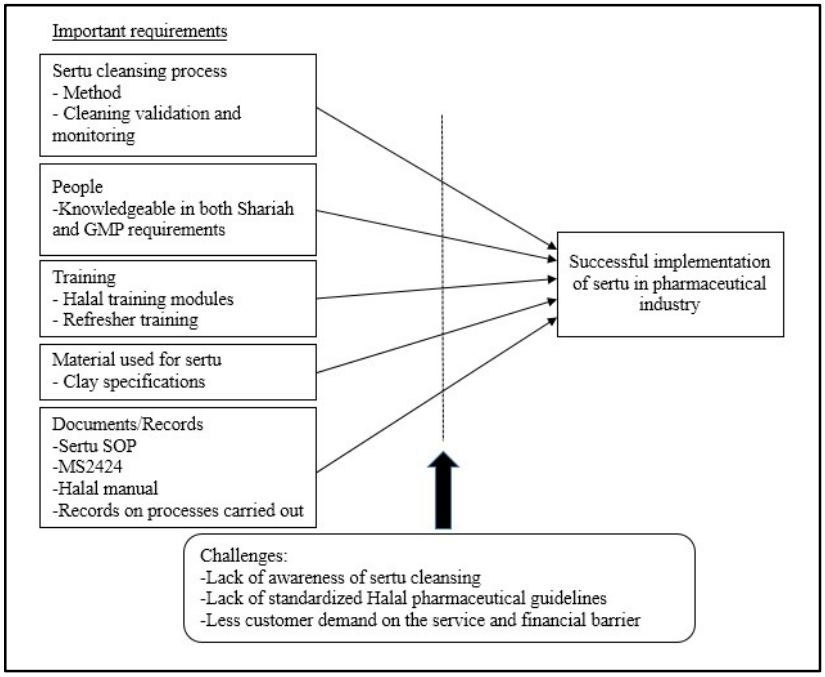

Figure 1: Proposed conceptual framework for important requirements and challenges in *sertu* implementation in pharmaceutical industry

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and JAIS), members of Halal Council and site Halal Committees, Group Halal Manager, production members, Quality Assurance (QA) members and Quality Control (QC) members were involved in the *sertu* implementation of Company B. Exchange of knowledge between the employees and staff from JAIS occur along the process (Figure 1).

Training

One of the participants from Company A mentioned that all employees including cleaners and non-Muslim employees were provided with two hours training (including evaluation) on introduction of halal and *sertu* SOP, in addition to the yearly refresher training. Other than that, an induction program also is provided for new employees. An external trainer from HDC also was invited to provide halal training modules for the employees in the company. On the other hand, the participant from Company B stated that practical guidance and training were provided by JAIS for members of Halal Council and site Halal Committees, Group Halal Manager, production members, QA and QC. The training was conducted not later than the day before *sertu* was conducted. Refresher trainingalso was provided for the staff. According to Ahmad&Mohd, 2016, suggested that training could contribute to a successful halal ritual cleansing implementation by enhancing halal integrity through creating awareness among employees (Figure 1).

Records

Standard Operating Procedure (SOP) for cleaning and for *sertu*, Halal Assurance System (HAS) and other documents such as halal manual, MS2424, and work instruction were used to guide the *sertu* process in Company A. SOP on how to purchase items such as raw materials and packaging materials was referred to guide the purchasing process. A plan with proper timeline that includes the date for conducting actual *sertu* process and when it has been planned was prepared earlier by the employee. In Company B, checklists and reports were prepared to ensure the *sertu* process adhered to GMP requirements and a proper documentation for shariah requirements has been done for future references. Any documents on *sertu* were prepared by halal executive and verified by shariah advisor and technical advisor, whereas any documents related to GMP were prepared by QC personnel and verified by QA head (Figure 1).

Materials used for Sertu

Fine clay powder together with the Certificate of Analysis (COA) and Material Safety Data Sheets (MSDS) that *provide information about specifications and safety status of the clay* were provided by JAIS before *sertu* was conducted in Company A. According to people in charge, 2015, any processing aids, hazardous materials, other special materials, or materials transferred to another unit within the company's control are not required to undergo testing if the manufacturer's certificate of analysis is obtained. In Company B, the water and clean clay powder that were used for the *sertu* process had been earlier approved by the competent authorities which are JAKIM, MAIS, and JAIS. The clay undergone microbial test before and after sterilization to ensure the safe use of the clay. Sterilization by autoclave was conducted on the clay before it was used for the *sertu* process. The clay should pass the tests required by GMP guidelines before it can be used in the *sertu* process. It should meet the required criteria in terms of low heavy metal contaminants, slightly acidic to neutral pH, fine particle size and low moisture content so that it would fulfill the standard halal requirements on quality and safety of the products (9).

Impact of *Sertu* Implementation to the Good Manufacturing Practice (GMP) Status in the Selected Pharmaceutical Companies

In order to comply with all GMP requirements, Company B ensured that the equipment, utilities, utensils and clothes used in the *sertu* process follow the

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pharmaceutical standard. Cleansing of equipment was conducted in washing areas that comply with GMP standard to prevent any cross contamination occurs. Appropriate gown was worn during the *sertu* process. GMP cleaning and environmental monitoring was conducted after *sertu* cleansing has been completed. Microbial test was conducted on the clay before and after sterilization as required by GMP guideline. The participants from Company A said there was no issue on *sertu* cleansing raised by theregulatory authorities and health authorities (e.g. Kementerian Kesihatan Malaysia (KKM), GMP, Scientific and Industrial Research Institute of Malaysia (SIRIM), National Pharmaceutical Regulatory Agency (NPRA), ISO 9001, ISO 70025, ISO 4001, ISO 14001, and ISO 17025). There was also no issue raised by the auditors from other countries as well such as Pfizer. Other than that, the process didnot cause any damageand scratch to the equipment because fine particles of clay were used for the *sertu* process.

Specific Issue/s and Challenge/s in Implementation of *Sertu* Procedures in Selected Halal Pharmaceutical Companies

The issues faced by the participants are listed, compared and any repeated issues are removed from the lists. Table 2 shows the listing of issues faced in *sertu* cleansing in halal pharmaceutical industry. All issues are coded Issue # and classified into categories coded as Barrier #.

All the above issues are then grouped into three larger groups of issues.

Table 2: Issues faced in sertu implementation in halal pharmaceutical industry

Codes	Issues Identified
Issue 1	Lack of knowledgeable person in charge of halal related matters (eg.*Sertu* cleansing) at the beginning
Issue 2	Lack of information available on *sertu* implementation in pharmaceutical settings
Issue 3	No experience performing *sertu* cleansing in pharmaceutical settings
Issue 4	No example of *sertu* cleansing in halal certified pharmaceutical company as a benchmark
Issue 5	Lack of industrial awareness of the halal concept throughout the whole supply chain
Issue 6	*Sertu* is an expensive method; not cost-effective (eg. Off operation for a week, discard non-halal materials, change of gowning)
Issue 7	Increase in workload before (eg. Set up tent, arrangement of equipment) and after *sertu* (eg. GMP cleaning)
Issue 8	Time-consuming (eg. New media validation, cleaning of small apparatus)
Issue 9	Existing references (eg MS2424, *sertu* SOP) are too general
Issue 10	Lack of standardized halal pharmaceutical guidelines
Issue 11	Lack of samak clay standard
Issue 12	Difficulty to look for the right *sertu* material that comply with GMP (sterilized) and Shariah (‘an acceptance) requirements
Issue 13	Problems in finding competitively priced halal-certified suppliers
Issue 14	Problem with current suppliers (eg non-muslim suppliers)
Issue 15	Lack of economy of skill since halal pharmaceutical is still in the infancy
Issue 16	Halal is currently not considered as a preferential criterion in the purchasing of pharmaceutical products

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Issues 1, 2, 3, 4 and 5 are grouped in Barrier 1 which indicates the lack of awareness of *sertu* cleansing by the halal certified pharmaceutical industry players and Muslim consumers. Issues 9, 10 and 11 are grouped in Barrier 2 which specifies the issues with the standard. Issues 6, 13, 14 and 15 are grouped in Barrier 3 which concerned with financial issues in *sertu* implementation in halal pharmaceutical industry. The result is as shown in Table 3 (27).

Barrier 1 discusses the awareness among halal pharmaceutical industry players and Muslim consumers. Studies fromMahidinet al (28) and Wahab (29) described lack of knowledge, awareness and understanding of the halal concept among Muslimconsumers and the manufacturers may become the reason for the loss of appreciation to halal. As mentioned by participants from Company B, halal is currently not a preferential criterion in the purchasing of pharmaceutical products. Lack of industrial awareness is not limited to food and beverages, or porcine and alcohol-based materials, but throughout the whole supply chain. Other than that, the participants from Company A and B mentioned that there isalso a lack of relevant information on *sertu*cleansing for pharmaceutical settings that could be obtained from other sources (e.g. internet). The participants from Company A described the difficulty of implementing*sertu* in the organization at beginning due to the absence of knowledgeable person in halal related matters among them. They also were unable to set other companies as a role model due to the confidentiality of the information needed from them.

Barrier 2 explains the issues related to the standard on halal pharmaceuticals. The participants from Company A and B commented on MS2424 which are too general and not standardized between countries. They were not convinced with the products from other countries in the market and there were also some complaints received from other countries due to the different guidelines used between countries as well. As proposed byNasaruddin et al (30) there are still insufficient development of

Table 3: Categories of issues in sertu implementation in halal pharmaceutical industry

Lack of awareness of sertu cleansing by the halal certified pharmaceutical industry players and Muslim consumers (Barrier 1) ▪ Lack of knowledgeable person in charge of halal related matters (eg.Sertu cleansing) at the beginning (Issue 1) ▪ Lack of information available on sertu implementation in pharmaceutical settings (Issue 2) ▪ No experience performingsertu cleansing in pharmaceutical settings (Issue 3) ▪ No example ofsertu cleansing in halal certified pharmaceutical company as a benchmark (Issue 4) ▪ Lack of industrial awareness of the halal concept throughout the whole supply chain (Issue 5)
Issues with the standard (Barrier 2) ▪ Existing references (eg MS2424, sertu SOP) are too general (Issue 9) ▪ Lack of standardized halal pharmaceutical guidelines (Issue 10) ▪ Lack of samakclay standard (Issue 11)
Financial issues (Barrier 3) ▪ Sertu is an expensive method; not cost-effective (Issue 6) ▪ Problems in finding halal-certified suppliers (Issue 13) ▪ Problem with current suppliers (eg non-muslim suppliers) (Issue 14) ▪ Lack of economy of skill since halal pharmaceutical is still in the infancy (Issue 15)

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halal procedures as well as guidelines from the ground up and current guidelines are still lacking halal concept. Consequently, Muslims have put less attention on halal production, and they are still facing halal problems. Lack of standardized halal guidelines also could lead to prolonged process and higher costs of production(21). Other than that, the participants from Company A also mentioned the lack of samakclay standard that can be used for validation purposes. A specific samak clay standard for industrial application is needed to meet the halal requirement and alsothe specifications of the equipment or machines(27).

Barrier 3 discusses the financial issues encountered to implement *sertu* in pharmaceutical industry. Participants from Company B commented on*sertu* as an expensive method because they have to stop production for a week. In addition, they also expressed the difficulty in findinga competitively priced halal certified ingredient supplier. The statement was supported by participants from Company A which found that looking for a halal certified supplier was time-consuming.Other than that, they also need to remove all non-halal materials, and make changes of gowning before they come up with the decision to establish a halal-certified company. The scenario stated above is supported by Hanzaee&Ramezami (14) which mentioned about some pharmaceutical companies that need to invest more in order to replace the ingredients that do not meet the criteria underlined by the guidelines which have been identified during ingredient's information review and the facility audit.

Conclusion

In order to meet consumers' demand on halal pharmaceuticals, pharmaceutical companies need to strictly follow the requirements highlighted by halal pharmaceutical standards MS2424. This include the need to ritually clean the equipment, machine appliances and processing aids which have been contaminated with non-halal substances. For the first research question, five requirements that contribute to the successfulness implementation of *sertu* in halal pharmaceutical industry were identified. The five requirements including process, people, training, records, and material for cleansing. A conceptual diagram was developed from the findings. For the second research question, the effect of *sertu* cleansing on GMP was examined. It is clear that *sertu* cleansing does not affect the GMP status nor cause any damage to the sensitive machines due to the use of clay in the cleaning process and is safe for the pharmaceutical products. For the third research question, there are three issues have been identified in *sertu* cleansing implementation in halal pharmaceutical industry. These issues are lack of awareness of *sertu* cleansing by the halal pharmaceutical industry players and Muslim consumers (Barrier 1), issues with the information in standards (Barrier 2), and financial issues (Barrier 3). These issues need to be addressed and further studied in order to implement *sertu* successfully in halal pharmaceutical industry.

This study is expected to provide insight on *sertu* cleansing in halal pharmaceutical industry that can be referred by future researchers and other pharmaceutical manufacturers that might be interested in halal pharmaceuticals production. This indirectly helps in the development of halal pharmaceuticals industry in Malaysia.

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