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Qualitative study on processes, issues and challenges in implementation of islamic obligatory cleansing (Sertu) in halal pharmaceutical industry

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Abstract---Islamic obligatory cleansing known as *sertu* in Malay language is one of the essential elements to ensure the halal integrity of products including in pharmaceuticals [1], [2]. It is an islamic cleansing required to be conducted when tools and equipment in the production facility are contaminated with severe najas (*Naj Mughallazah*) which are of pork or dog-based contaminant. Islamic law has prescribed the way to cleanse *Naj Mughallazah* by using one time of clay and clean water suspension followed by six times of rinsing with pure water (*mutlaq*) [3]. The study on the implementation of *sertu* cleansing especially in halal pharmaceutical industry is very limited if any [4]. Hence this study was conducted to explore the process, issues, and challenges as well as to discover the success factors in the implementation of *sertu* cleansing in pharmaceutical facilities from the perspective of *sertu* providers. This study used the qualitative in-depth interview and purposive sampling technique

where participants were selected among *sertu* providers who have the experience of conducting *sertu* cleansing in pharmaceutical facilities. Data were analysed using thematic analysis and validated through triangulation with data from a few sources. The result of this study found that different *sertu* providers used different approach and procedures in implementing the *sertu cleansing*. This might be due to an absence of comprehensive procedures established on *sertu* specifically for pharmaceutical industry which involved delicate machines. A few issues and challenges were identified which could be overcome by the success factors. A *sertu* cleansing framework is proposed from the outcome from the study. In the depth understanding it is important to develop standardized *sertu guidelines* specific for halal pharmaceutical industry. The proposed *sertu* cleansing framework provides an overview of the *sertu* cleansing process flow as a more refined reference to supplement MS2424: Halal Pharmaceutical Standards *sertu* cleansing guideline.

Keywords---*Sertu* ;Clay; Najs; Islamic ritual cleansing; Halal pharmaceutical general guidelines, MS 2424.

Introduction

Halal pharmaceutical is starting to get a place in the pharmaceutical market and is well-accepted among Muslim and non-Muslim consumers. To be halal certified by JAKIM (Department of Islamic Development Malaysia) the agency responsible for the Islamic affairs in Malaysia, the emphasis is not only on the origin of the ingredients but also the manufacturing process must comply with the requirements set in the Malaysian Standard MS2424:2012, Halal Pharmaceutical-General Guidelines. According to MS2424:2012, *sertu* cleansing need to be conducted if contamination with severe najis (Najis *Mughallazah*) which consist of porcine or canine-based materials occurs. However, there have been very few studies conducted on halal pharmaceuticals especially on *sertu* cleansing in pharmaceutical industry.

1.1. Problem Statement

Sertu is required to ensure cleanliness against severe najis (najis *Mughallazah*) contamination. But, according to [5], the awareness on the *Sertu* cleansing operations in Malaysia among industry players is relatively low. This is especially true for the pharmaceutical industry. The *sertu* guideline as described in MS2424 is very brief and how it is implemented in the highly regulated pharmaceutical plants has not been explored in detail. Hence the study to explore the implementation of *sertu* in the pharmaceutical industry is required to fill the knowledge gap in this area.

1.2. Research Objective

The aim of the study is to provide a thick description on how *sertu* cleansing process is being implemented in the halal-certified pharmaceutical facilities to

comply with the halal certification requirements and to ensure halal integrity of the halal pharmaceuticals, as well as to explore the issues, challenges and success factors in implementing of MS2424 *Sertu* guidelines in pharmaceutical industry.

1.3. Significance of the Study

There are very few studies on halal pharmaceuticals, especially on *sertu*. Hence findings from this study provided the thick description and process flow for *Sertu* implementation in Halal pharmaceutical which can be used as a reference by the pharmaceuticals industry and provided the body of knowledge on the *sertu* implementation process, issues, and challenges. This, in turn, can promote adoption of Halal pharmaceutical within the pharmaceutical industry.

1.4. Literature Review

1.4.1. Definition of Halal

Halal means that the things or actions are permitted or lawful to be consumed and being used by the Muslim. Meanwhile, haram means that the things or actions are forbidden and unlawful [6]. In Malaysian Standard MS2393, on Islamic and halal principles - Definitions and interpretations on terminology [7], Halal is defined as an act or product that is lawful and permitted in Islam based on the authoritative sources and it is the opposite of haram.

According to the Malaysian Halal Pharmaceutical Standards MS2424 [3], the Halal pharmaceutical product is defined as the product that

- I. do not contain any parts or products of animals that are non-halal by Sharia law or any parts or products of animals which are not slaughtered according to Sharia law;
- II. do not contain najis according to Sharia law;
- III. safe for human use non-poisonous, non-intoxicating or non-hazardous to health according to prescribed dosage;
- IV. not prepared, processed or manufactured using equipment contaminated with najis according to Sharia law;
- V. do not contain any human parts or its derivatives that are not permitted by Sharia law; and
- VI. during its 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 I), II), III), IV) or V) or any other items that have been decreed as non-halal and najis by Sharia law.

Halal pharmaceuticals provide a way for Muslim consumers to preserve their faith and belief even in healthcare practices [8]. 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 [9]. Halal pharmaceuticals are produced based on the harmonization of Islamic religious law, GMP standards as well as the approved halal supplier and material list [10].

1.4.2. Najs Definition and Categories

According to the Islamic law, najs is defined as something dirty and disgusting [7]. If a Muslim is in contact with najs, the cleansing process needs to be done before proceeding to religious duties such as prayer [6].

There are three types of najs, which are *Mughallazah*, *mukhaffafah* and *mutawassitah*. *Mughallazah* is considered as severe najs which are dogs and pigs (khinzir) including any liquid and objects discharged from their orifices, descendants, and derivatives. Next, *mukhaffafah* is considered as light najs. The only najs in this category is urine from a baby boy at the age of two years and below who have not consumed any other food except his mother's milk. Lastly is *mutawassitah* which is considered as medium najs. It does not fall under severe or light najs such as vomit, pus, blood, khamar, carrion, liquid and objects discharged from the orifices [11].

Najs can also be classified into two different types based on its physical existence which are visible najs (*'ainiyah*) and Invisible najs (*hukmiyah*). Najs that appeared physically present in the stool can be seen and touched is called visible najs (*'ainiyah*). Meanwhile, invisible najs (*hukmiyah*) are najs that have lost the physical form, dried or something else [3], [7], [11], [12].

1.4.3. Sertu Cleansing (Islamic Halal Cleansing)

According to Islamic Shariah law, there is a special method called for Islamic cleansing to clean against najs *Mughallazah* or severe najs derives from dog, pig and its descendants which we called *sertu* in Malay language. The *sertu* cleansing from *Mughallazah* najs is the act of cleansing with the intention of purifying the body, clothing, spaces, utensils and equipment that was in contact with *Mughallazah* najs; by washing seven times using *mutlaq* (pure uncontaminated and clean) water. The first wash being with water mixed with soil [2].

In Malaysian Standard MS2424:2012, *sertu* is referred to as Islamic ritual cleansing while in the Malaysian Standards for Halalan-Toyyiban Assurance Pipeline -Part 1: Management System Requirements For Transportation Of Goods And/Or Cargo Chain Services (MS2400-1:2010) *sertu* is referred as Shariah ritual cleansing which is an act to the remove contaminants based on cleansing procedures in accordance to the Shariah requirements as stipulated in MS2400-1 standard requirements [2].

There are very few publications on *sertu* for which if any are mainly for logistics or general halal industry [1], [2], [6], [13]. However, the study on *sertu* in the pharmaceutical industry has not been found. In one of the publications, Ahmad &

Shariff (2016), claimed that the awareness on the *Sertu* cleansing operations in Malaysia among the logistics industry players is relatively low and there is also a lack of integration and collaboration between industry and Halal authority in *Sertu* implementation [2], [5]. They also found that there is less discussion on the challenges in *sertu* or samak cleansing on transport vehicles and container in upholding the halal integrity of goods from the farm to fork in these publications [2]. This scenario seems to be also true for the pharmaceutical industry.

Therefore, more studies on *sertu* implementation in various type of industries should be done to close the knowledge gap and also to increase the Muslim customers' awareness of *sertu* or samak cleansing is needed because it is one of the elements in ensuring the halal status of the product.

Table 1 below is the list of publications on the *sertu* or samak to date.

Table 1 List of publication on *sertu* or samak to date

No	Title	Author	Name of Journal or event and Year	Summary
1	<i>Sertu</i> Cleansing Operations Towards Halal Integrity: A Literary Insight	Noorsiah Ahmad, Sariwati Mohd Shariff	2nd Business Management and Computing Research Colloquium, July 2017	This study explores the literary review of the <i>sertu</i> cleansing operations process. It related policies and procedural requirements, as stated in the Malaysian Standards MS2400:2010 for halalan-toyyiban assurance pipeline or known as the halal supply chain management.
2	Conceptual Framework on Halal Ritual Cleansing Integrity in Halal Logistics	Noorsiah Ahmad, Sariwati Mohd Shariff	Proceedings of the 2nd UUM International Qualitative Research Conference, 24-26 May 2016. Penang, Malaysia. Available online at www.qualitative-research-conference.com	This is a concept paper attempts to discuss on factors in halal ritual cleansing integrity, known as <i>sertu</i> cleansing covering halal procedure and documents; process or method of <i>sertu</i> cleansing; people engaged in these

				activities; and the <i>sertu</i> cleansing products towards assuring integrity of halal product supply chain in the real market.
3	Challenges on <i>Sertu</i> Cleansing in Halal Logistics	Noorsiah Ahmad, Sariwati Mohd Shariff	Journal of Applied Environmental and Biological Sciences 6(11S)31-39, 2016	This paper describes four challenges identified, faced by halal logistics service providers.
4	Supply Chain Management: <i>Sertu</i> Cleansing for Halal Logistics Integrity	Noorsiah Ahmad, Sariwati Mohd Shariff	Procedia Economics and Finance (2016) 37 418-425	This literary paper aims to provide a literature review on halal <i>sertu</i> cleansing for halal integrity in supply chain management.
5.	New Approach of Samak Clay Usage for Halal Industry Requirement	Norrahimah Kassim, Puziah Hashim Dzulkiily Mat Hashim, Hamdan Jol	Procedia - Social and Behavioral Sciences 121 (2014) 186 – 192	This is a study of samak clay as the potential industrial Islamic cleansing application.
6.	Study on the Requirement of Clay for Islamic Cleansing in Halal Food Industry	Norrahimah Kassim, Puziah Hashim Dzulkiily Mat Hashim, Hamdan Jol	The Online Journal of Science and Technology- July 2013, Volume 3, Issue 3	This paper is a study of clay requirements for Islamic cleansing for its usage in the Halal food supply chain.

1.4.4. MS 2424:2012 Halal Pharmaceutical-General Guidelines

MS2424:2012; Halal pharmaceutical- general Guideline is a general guideline on halal pharmaceutical introduced to the pharmaceutical industry in Malaysia in the year 2012. It became the first halal pharmaceutical standard available in the world. This guideline is to ensure the halal pharmaceutical companies in Malaysia are all up to the same standard. It describes the general guideline in manufacturing and handling of halal pharmaceutical and serves as a basic requirement for halal pharmaceutical in Malaysia as well as a brief information on how to conduct the ritual cleansing.

2. Materials and Methods

2.1. Study Design

The main objective of this study is to discover the process, issues, and challenges in the implementation of MS2424 *Sertu* guidelines in the pharmaceutical company from the perspective of the *sertu* provider. This is an exploratory study as not much is known about the implementation of *sertu*, especially in the highly regulated pharmaceutical industry. The qualitative case study is the most suitable for this research project as a case study is usually used to get in-depth details as much as possible about an event, person or process [14]. Qualitative case study facilitates the exploration of a phenomenon which in this case is the implementation of *sertu* within its context by using a variety of data sources [14].

2.2. Data Collection and Sampling Method

In this study, we conducted in-depth semi-structured interviews using a developed interview protocol. The data collection protocol and research design were submitted to CUCMS ethics committee review and approved before the data collection initiated. Purposive sampling was used to identify the target sample that gives the best and most in-depth, relevant information. As cited by [14], in a case study at least one individual may be interviewed as proposed by [15], [16]. In this study, three different participants from two distinct *sertu* providers which are known to have the knowledge and experience in conducting *sertu* at pharmaceutical manufacturing facilities were enrolled. The two *sertu* providers are selected as rich information and a thick description of the *sertu* implementation are practically available from them. Jette, Grover, and Keck (2003) suggested that expertise in the chosen topic can reduce the number of participants needed in a study [17] hence the number of participants in this study should be sufficient to provide the required information. The interviewed participants are the persons with authority, knowledge, and experience to provide the information on behalf of their respective companies.

Table 2 showed the samples chosen that believed have provided rich information on *sertu* implementation in halal pharmaceutical.

Table 2 Selected participants from *sertu* provider to pharmaceutical companies in Malaysia

Participants	Company	Description	Position	Years in industry
P1	<i>Sertu</i> Provider 1 (SP1)	<i>Sertu</i> provider and policymaker.	Officer	16
P2	<i>Sertu</i> provider 1 (SP1)	<i>Sertu</i> provider and policymaker.	Assistant Officer	9
P3	<i>Sertu</i> Provider 2 (SP2)	Commercial <i>Sertu</i> provider and producer of <i>sertu</i> clay	Chief Operating Officer	4

Data was collected through in-depth face to face interview as the primary source of data collection and documents as a secondary source. Face to face interviews was done at the participant's office and away from distraction. The duration of the interviews lasted for a few hours depending on the participant's comfortability and response. Usually, it took around two to three hours plus resting time in between the conversation. The interviews were conducted in Malay and English and voice recorded with consent. The recorded interview then transcribed and analysed.

2.3. Data Analysis Method

The data collected through document reviews and transcribed interviews were analysed using thematic analysis. Through thematic analysis, the key concepts or code from the studies were identified, and then the same concepts available in other studies were identified. The same concepts were then pulled together to develop a theme [18], [19]. Three stages were involved in the data synthesis. Firstly, line-by-line coding of the data was done and the similarities and differences between the codes were reviewed for data grouping purposes. Secondly, the codes then organised into related areas so that 'descriptive' themes can be developed then finally themes were developed for analysis [19]. In this study, the coded lines were grouped into predetermined themes such as process, issues, and challenges as well as success factors. The data from this study were validated through triangulation method where data collected from different sources and from different participants were compared for convergence or non-convergence [18].

3. Results and Discussion

3.1. Sertu Cleansing Process

Through the literature review, it has been described that generally Najs *Mughallazah* either visible or invisible can be cleaned by seven times washing with one of it is with water mixed with clay. Any existence of najis needs to be cleaned first before proceeding with the *sertu* cleansing. In the implementation of *sertu* the specification of the clay and water to be used are as follows [3], [12]:

3.1.1. Clay specification

The conditions of the soil shall be:

- i. Free from najis
- ii. Free from contaminants
- iii. Not musta'mal soil [which had been used for dry ablution (tayammum)] except after subject to heavy rain.

3.1.2. Water specification

The conditions of the water are:

- i. Shall be natural (mutlaq);
- ii. Not *musta'mal and
- iii. Free from najis

*Musta'mal water is the water that is less than two qullah (approximately 192 litres) that had been used for cleansing.

In actual setting, the steps in detail from initiation to completion of the *sertu* process as described by SP1 and SP2 are as illustrated in figure 1 and figure 2 below.

Fig. 1. *Sertu* cleansing service process flow provided by SP1.

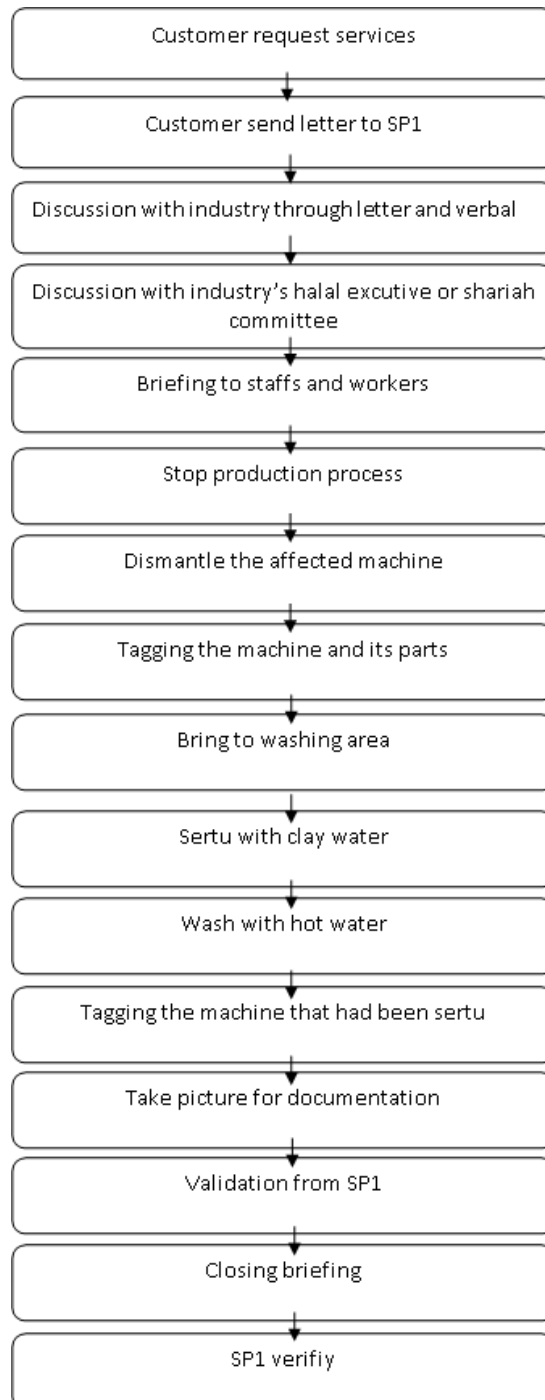


Fig. 1 showed the flow chart of *sertu* process done by SP1 as shared by the participant. When there is a need for *sertu* cleansing, customers will request in writing to SP1. This then followed by verbal and written discussion on the location of the affected area, the contaminated machine, type of machine affected, severity of the contamination and how *sertu* will be applied to cleanse the najis *Mughallazah* before they proceed with other steps as in figure 1 above.

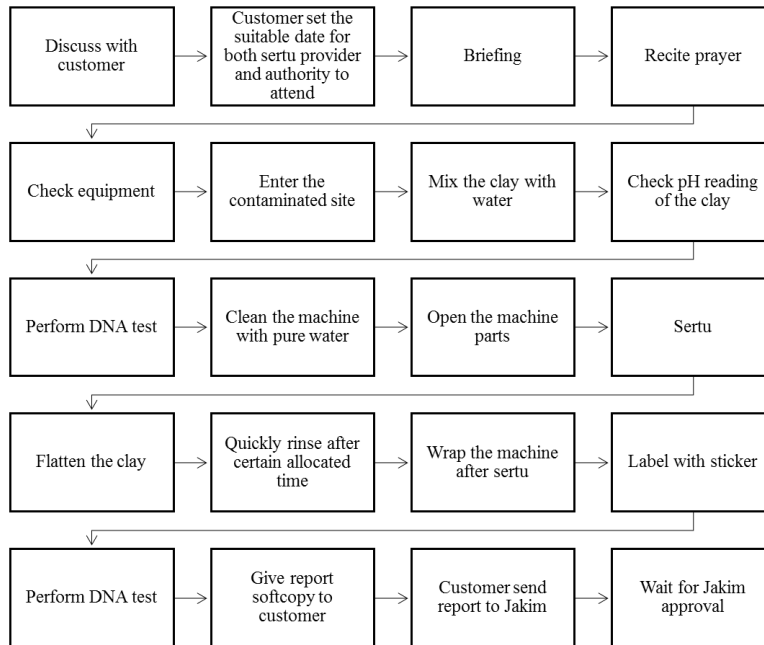


Fig. 2. *Sertu* cleansing service process flow provided by SP2.

On the other hand, Fig. 2 presented the *sertu* cleansing service process sequence as shared by SP2. Following customer request and discussion, the customer together with *sertu* provider (SP) needs to set a date to conduct the *sertu* on a day that the authority from State Islamic Affairs can come and witness the whole procedure. On the allocated date, *sertu* cleansing will be done by SP2 and will be observed by the authority for validation and verification of the *sertu* process accomplishment.

From the above description, we can see that different *sertu* provider have a different approach as well as different added value services such as the DNA testing, in meeting their customer needs in addition to the main cleansing activity. It is up to the customers' needs, budget and available time to decide on which service provider would be more suitable for them. The most important thing is that the contaminated area and equipment have been cleaned as prescribed by the shariah requirement.

In addition to the macro view of the sequential steps upon receipt of a *sertu* cleansing service request, the actual method on conducting the *sertu* cleansing process for the different type of machines may vary depending on the type of

machine and equipment, their tools size, and sensitivities. Fig. 3 below summarises the different approach taken in conducting the *sertu* cleansing based on the normal practice shared by both *sertu* providers.

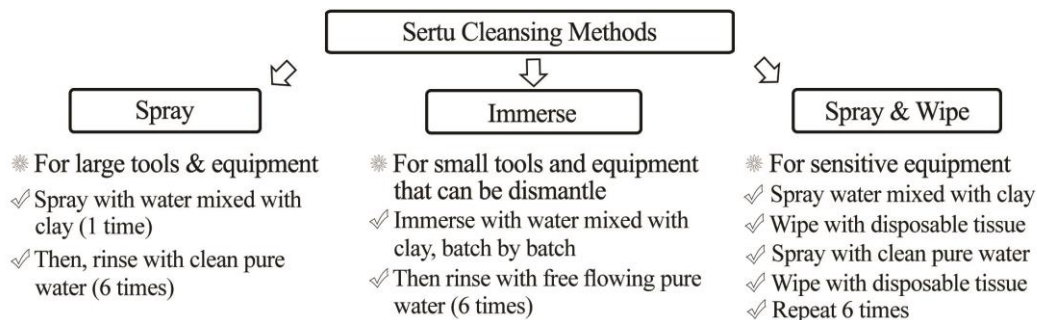


Fig. 3. The three approaches in conducting *sertu* cleansing

As can be seen in Fig. 3, both SP1 and SP2 used these three different *sertu* cleansing approaches, depending on the nature of the equipment or tools to be cleansed. Both *sertu* providers will visit and inspect the premise to be cleansed before the actual day to determine the best approach and tools required for the conduct of the *sertu* cleansing at the required site.

From the elaborated description on *sertu* cleansing implementation above, the pharmaceutical industry could have a better overview on the extent of effort and initiative required to conduct *sertu* cleansing, as well as providing some indication on the safety measures and consideration already taken into consideration before conducting *sertu* cleansing. Generally, the process is secured and there was no reported major breakdown due to *sertu* faced by the *sertu* provider.

3.2. Issues and Challenges

Issues and challenges are categorised using the method proposed by [19]. Issues faced by *sertu* provider were listed, compared and any similar or repeated issues were filtered and removed from the lists. Table 3 shows the listing of issues that are being faced by *sertu* provider. Based on the lists, all issues are coded ISSUE # and categorised into categories, coded BARRIER #.

Table 3 Issues faced by *sertu* provider in implementing *sertu* in pharmaceutical industry

Code	List of Issues
ISSUE 1	Lack of comprehensive <i>sertu</i> guideline to conduct <i>sertu</i> for pharmaceutical
ISSUE 2	Lack of management structure in <i>sertu</i> provider organization in conducting <i>sertu</i> .
ISSUE 3	Lack of knowledgeable and expert's person in implementing

sertu for pharmaceutical settings

- ISSUE 4 Deficiency of documentation and record keeping of *sertu* procedure.
- ISSUE 5 Lack of personnel manpower to conduct *sertu* in pharmaceutical settings
- ISSUE 6 Lack of awareness on *sertu* cleansing and its importance in the pharmaceutical industry
- ISSUE 7 Lack of awareness towards *sertu* implementation among Malaysian
- ISSUE 8 Lack of technical knows how to conduct *sertu* in pharmaceutical settings especially involving sensitive machinery.
- ISSUE 9 Time-consuming in conducting *sertu* for the pharmaceutical industry
- ISSUE 10 Unclear custodian on record on communication tracking on *sertu* implementation.
- ISSUE 11 The standard operating procedure for *sertu* is too general
- ISSUE 12 Lack of standardized fees for *sertu* provider
- ISSUE 13 Insufficient skill to explain to non-Muslim about *sertu* implementation in pharmaceutical settings
- ISSUE 14 The absence of technical parameters standardization to conduct *sertu* in pharmaceutical settings (eg. Water flow rate, pressure, temperature, pH, clay concentration)
- ISSUE 15 Time constraint
- ISSUE 16 High Electricity-consumption when conducting *sertu* in large scale in pharmaceutical settings
- ISSUE 17 Large water-consumption when conducting *sertu* in a large scale of pharmaceutical settings
- ISSUE 18 Lack of research on *sertu* implementation for pharmaceutical settings
- ISSUE 19 Lack of standard team members to conduct *sertu* in the pharmaceutical industry within the *sertu* provider organization.

ISSUE 20	Non-compliance of industry on <i>sertu</i> implementation
ISSUE 21	Lack of insurance coverage for <i>sertu</i> provider when conducting <i>sertu</i> in pharmaceutical settings
ISSUE 22	Lack of personnel capacity in handling large machine and equipment in pharmaceutical settings during <i>sertu</i> implementation.
ISSUE 23	Lack of integrity in handling <i>sertu</i> for pharmaceutical
ISSUE 24	Lack of support from authority to <i>sertu</i> provider
ISSUE 25	<i>Sertu</i> procedure may not be cost-effective and use large amount of expenditure
ISSUE 26	Different <i>sertu</i> cleansing approach used by different <i>sertu</i> provider for pharmaceutical
ISSUE 27	Lack of cooperation between <i>sertu</i> provider and <i>sertu</i> related authority
ISSUE 28	Lack of enforcement to maintain the halal integrity
ISSUE 29	Task specialization issues between the <i>sertu</i> provider and state Islamic affairs division in <i>sertu</i> implementation.
ISSUE 30	Difficulty of <i>sertu</i> provider to get an endorsement from the authority on the completed <i>sertu</i> process.
ISSUE 31	Some company cannot stop the production line during <i>sertu</i> implementation
ISSUE 32	Authority certify their own <i>sertu</i> process
ISSUE 33	Risk of bacterial contamination.

All issues encountered by the *sertu* providers are then categorised into seven categories of BARRIERS as in table 4 below.

Table 4 Categories of issues faced by *sertu* provider

BARRIER 1: Awareness on <i>Sertu</i>	
Lack of awareness on <i>sertu</i> cleansing and its importance in the pharmaceutical industry	ISSUE 6
Lack of awareness on <i>sertu</i> implementation among Malaysian public.	ISSUE 7
BARRIER 2: Standards, Guidelines&Technical Information	

Lack of comprehensive <i>sertu</i> guideline to conduct <i>sertu</i> for pharmaceutical	ISSUE 1
The <i>sertu</i> guideline in Malaysian standard for <i>sertu</i> is too general	ISSUE 11
A different <i>sertu</i> cleansing approach used by different <i>sertu</i> provider for pharmaceutical	ISSUE 26
Lack of knowledgeable and expert person in implementing <i>sertu</i> for pharmaceutical settings	ISSUE 3
Lack of technical knows how to conduct <i>sertu</i> in pharmaceutical settings especially involving sensitive machinery.	ISSUE 8
Insufficient skill to explain to non-Muslim about <i>sertu</i> implementation in pharmaceutical settings	ISSUE 13
The absence of technical parameters standardization to conduct <i>sertu</i> in pharmaceutical settings (eg. Water flow rate, pressure, temperature, pH, clay concentration)	ISSUE 14
Lack of research on <i>sertu</i> implementation for pharmaceutical settings	ISSUE 18

BARRIER 3: Financial Barrier

Lack of standardized fees for <i>sertu</i> provider	ISSUE 12
<i>Sertu</i> procedure may not be cost-effective and used a large amount of expenditure	ISSUE 25
Electricity-consuming when conducting <i>sertu</i> in a large scale of pharmaceutical settings	ISSUE 16
Large water-consuming when conducting <i>sertu</i> in a large scale of pharmaceutical settings	ISSUE 17
Lack of insurance coverage for <i>sertu</i> provider when conducting <i>sertu</i> in pharmaceutical settings	ISSUE 21

BARRIER 4: Cooperation and Support between Authority and *Sertu* Provider

Lack of support from authority to <i>sertu</i> provider	ISSUE 24
Lack of cooperation from authority to <i>sertu</i> provider	ISSUE 27
The difficulty of <i>sertu</i> provider to get accreditation from authority	ISSUE 30
Task specialization issues between the <i>sertu</i> provider and state Islamic affairs division in <i>sertu</i> implementation.	ISSUE 29

BARRIER 5: Documentation & Record Issue

Deficiency of structured documentation on <i>sertu</i> implementation	ISSUE 4
Unclear custodian on record on communication tracking on <i>sertu</i> implementation.	ISSUE 10

 BARRIER 6: Manpower

Lack of personnel manpower to conduct <i>sertu</i> in pharmaceutical settings	ISSUE 5
Time constraint	ISSUE 15
Lack of personnel capacity in handling large machine and equipment in pharmaceutical settings	ISSUE 22
Lack of standard team members to conduct <i>sertu</i> in the pharmaceutical industry	ISSUE 19

 BARRIER 7: Management & Operational Issue in handling *Sertu* in Pharmaceutical Settings

Lack of management structure of <i>sertu</i> providers organization in conducting <i>sertu</i>	ISSUE 2
Some company cannot stop the production line during <i>sertu</i> implementation	ISSUE 31
Time-consuming in conducting <i>sertu</i> for the pharmaceutical industry	ISSUE 9
Non-compliance of industry on <i>sertu</i> implementation	ISSUE 20
Lack of integrity in handling <i>sertu</i> for pharmaceutical	ISSUE 23
Lack of enforcement to maintain the halal integrity	ISSUE 28
Authority certify their own <i>sertu</i> process	ISSUE 32
Risk of bacterial contamination	ISSUE 33

BARRIER 1 showed that there is still a lack of awareness among the industry players and the Malaysian public on the *sertu* cleansing itself and its importance in ensuring the halal integrity of halal pharmaceuticals. The public may not even aware of the requirement to conduct *sertu* for manufacturers having contaminated equipment to get halal certified. Hence more halal and *sertu* awareness campaign should be conducted to create awareness and demand among the industry players and inquiry from the public to encourage *sertu* cleansing for better halal integrity.

BARRIER 2 indicate that while *sertu* guideline exists as an appendix to MS2424 and a general *sertu* guideline by JAKIM available, they however still lack on technical details required for conducting *sertu* in a highly regulated pharmaceutical industry which emphasize much on evidence-based activity. As an example, while SP2 used specific concentration of clay in pure water in conducting the first wash of the *sertu* cleansing, SP1 just add an amount of clay based on subjective judgment just enough to change the appearance of the pure water. SP2 claimed that they have the data which shows that the concentration that they are using is the minimal clay concentration which has showed optimal antibacterial activity. Therefore, JAKIM or relevant certification bodies should consider doing some research and discussion among them, on the necessity of setting the technical parameters such as water flow rate, clay concentration, water pH and so on, to convince and meet the requirement of the stringent multinational pharmaceutical companies with high regulatory requirements.

BARRIER 3 is the common concerns among industry players. The perception is *sertu* activity will incur a lot of costs, not only on the *sertu* service cost but also energy and resources expenses as well as production downtime. However pharmaceutical industry players should do a proper analysis as the cost incurred may not be that significant compared to the potential return on investment and the importance of meeting customers demand for halal medicines.

BARRIER 4 pertains support from the authority either JAKIM or from the State Islamic Affairs Halal Division. The general perception was that the support and cooperation with the authority are still not at the expected level causing some difficulty from the *sertu* providers' perception. The problem may be due to lack of capacity and division of task within the authority organization at the present moment.

BARRIER 5 is on documentation and records. There is a generally minimal record kept at SP1 as the expectation is the company which received the *sertu* service is the ones to keep the evidence that the company has done the *sertu* cleansing endorsed by the authority for halal certification application while SP2 keep a copy of the checklist and *sertu* service-related documents. Hence in terms of record keeping, there is no clear guideline on what kind of document and to what extent documents need to be kept as a satisfactory proof for certification application.

BARRIER 6 discusses the constraint in manpower supply to conduct the *sertu* . While SP1 received a lot of demand to conduct *sertu* from various type of industry including pharmaceutical, they have limited main power and time to fulfill the demand as *sertu* cleansing service is not their core business. SP2 is also facing the same constraint of insufficient manpower to meet the demand. However, efforts are being made by SP2 to recruit and train more companies under their control and supervision to conduct *sertu* to companies, not from their core business.

BARRIER 7 is regarding management and operational issues in handling *sertu* implementation. Among others, the operational challenge includes working at odd hours over extended hours and days due to suboptimal management structure and number of manpower and having to comply with the manufacturers' production schedule. The suboptimal structure and manpower open the risk to integrity and contamination issue during the conduct of *sertu* leaving one wonder whether the *sertu* cleansing has been done appropriately and covers all expected areas. In addition, the *sertu* cleansing service is conducted once upon request with no enforcement and monitoring afterward to ensure that the site maintains the halal integrity of the place. The authority may need to revisit this barrier to find the solution to ensure halal integrity is maintained.

3.3. Success Factors

Despite the many issues and challenges identified by the *sertu* cleansing has been successfully implemented in several halal certified pharmaceutical companies. The factors contributed towards successful implementation of *sertu* that have been shared by the SP1 and SP2 are as listed in Table 5.

Table 5 Success factors for implementation of *sertu* in pharmaceutical industry

No	Success Factors (SF) Required
SF1	Presence of halal executive within pharmaceutical companies.
SF2	Intensive <i>sertu</i> training to <i>sertu</i> provider
SF3	Establishment of detail standard operating procedure for <i>sertu</i> in pharmaceutical settings
SF4	Fees standardization for <i>sertu</i> provider
SF5	Effective two-way communication between authority and <i>sertu</i> provider
SF6	Successfully convince pharmaceutical company on the importance of <i>sertu</i> to maintain the halal integrity

4. Conclusion

The outcome from the study has provided an elaborated illustration and description on the sequence of steps and methods to use in conducting *sertu* in pharmaceutical facilities. This information can be used as the reference for other pharmaceutical companies which are considering going for *sertu* and halal certification but lacking sufficient information to make preparation in terms of energy, budget, and manpower before making decisions.

There are 7 barriers identified to be the main challenge in *sertu* implementation, however, the challenges may be overcome with the suggested of action items recommended under each barrier identified. Moreover, the six success factors identified may be optimized to overcome address the issues and challenges raised.

In summary, the findings from this study have provided more information to close the knowledge gap on *sertu* cleansing implementation in pharmaceutical industry, by providing thick description on how *sertu* process is done by different *sertu* providers, listed identified issues and challenges faced and sharing of key success factors which can help the successful growth of *sertu* cleansing implementation for better halal integrity maintenance in pharmaceutical companies. Further studies can be done in future researchers who wish to develop a structured *sertu* framework for the pharmaceutical application.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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Figure and Table legends

Fig. 1. *Sertu* cleansing service process flow provided by SP1.

Fig. 2. *Sertu* cleansing service process flow provided by SP2.

Fig. 3. The three approaches in conducting *sertu* cleansing.

Table 1 List of publication on *sertu* or samak to date.

Table 2 Selected participants from *sertu* provider to pharmaceutical companies in Malaysia.

Table 3 Issues faced by *sertu* provider in implementing *sertu* in pharmaceutical industry.

Table 4 Categories of issues faced by *sertu* provider.

Table 5 Success factors for implementation of *sertu* in pharmaceutical industry.