

# HALAL VACCINES COMPLIANCE WITH BRUNEI'S GD 24:2010 STANDARD GUIDELINES

Nur Nabiilah Haji Ramlli\*, Hamzah Mohd Salleh

Halalan Thayyiban Research Centre, Universiti Islam Sultan Sharif Ali, Negara Brunei Darussalam.

\*nabiilahhr.1005@gmail.com

## ABSTRACT

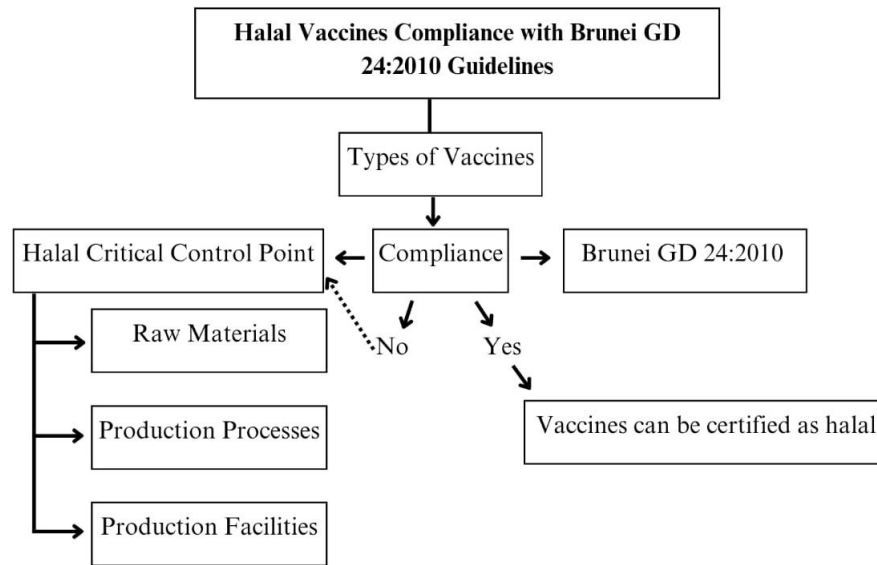
The increasing demand for halal certified vaccines highlights the need to align pharmaceutical production with Islamic principles. This research evaluates vaccine production processes for compliance with the standards that were outlined in Brunei's GD 24:2010 standard guidelines. By analysing patents and reviewing halal certification practices, this research identifies challenges and opportunities in ensuring the permissibility of vaccines and possibility of certifying the vaccines as halal under shariah law. The findings of this research aims to provide insights for the regulatory bodies, pharmaceutical manufacturers and policymakers to bridge the gap in halal vaccine production and certification processes

**Keywords:** *Brunei GD24:2010 Guidelines, Compliance, Halalan Thayyiban, Halal Vaccines*

## 1. Introduction

Over recent years, the rise in Muslim consumer awareness of halal pharmaceuticals has led to a significant expansion of halal pharmaceutical industry. A recent report indicated that Muslims spending on pharmaceuticals reached USD108 billion in 2022, and the value of halal pharmaceuticals is forecasted to reach USD142 billion in 2027 (2023/24 State of the Global Islamic Economy Report). The rise has prompted pharmaceutical companies to consider the halal status of their products particularly in medicines and vaccines to ensure acceptance within the global Muslim populations. For Muslims, it is essential to have halal assurance at every stage of manufacturing of products. With the growing potential success of the halal pharmaceutical industry, the establishment of appropriate laws and regulations would be beneficial (Raja Ikram, 2013). Thus, halal pharmaceuticals should not only comply with Islamic principles but also adheres to stringent safety and quality standards. Therefore, the integration of the concept of 'halalan thayyiban' principles in medicinal products is increasingly important to ensure that medicinal products such as vaccines are following the Islamic consumer and ethical standards.

Vaccines play an important role in public health by preventing the spread of infectious diseases. However, concerns about the inclusion of non-halal substances such as porcine-derived enzymes have raised concerns in Muslim communities. Moreover, the use of non-halal substances has led to scepticism on the permissibility under Shariah law. Additionally, sourcing of halal ingredients, risks of cross-contamination and lengthy certification processes further complicates compliance of vaccines. These concerns pose challenges in achieving herd immunity and maintaining public health. In this context, Brunei's "GD 24:2010 - Manufacturing & Handling of Halal Medicinal Products, Traditional Medicines & Health Supplements" standard guidelines serves as a critical benchmark for ensuring the permissibility and safety of vaccines.



**Fig. 1:** Conceptual Framework

Figure 1 illustrates the framework of this overall research study. It includes processes of determining whether vaccines can be certified as halal according to the standards outlined in Brunei's GD 24:2010 guidelines. The key point of this research is divided into three main aspects which are (i) Brunei's GD 24:2010 standard guidelines, (ii) compliance check, (iii) halal critical control point. First is to identify the types of vaccines which need to be assessed. The vaccines are then being evaluated for compliance with Brunei's GD 24:2010 guidelines, if the vaccines meet the compliance standards, they can be certified as halal. And if they do not meet the compliance standards, further assessment is needed by tracing the raw materials, production processes and production facilities of the halal critical control point (HCCP). The third key point is the HCCP where it involves assessing specific aspects of vaccine production beginning with raw materials by evaluating whether materials used in the vaccines are halal. It then proceeds with production processes by ensuring that the processes in the manufacturing of vaccines adhere to halal principles. Last is the production facilities by checking if the facilities where vaccines are produced comply with relevant halal standards.

Therefore, this research seeks to address these issues by evaluating vaccine production processes through the Brunei GD 24:2010 standard guidelines and identifying barriers to the implementation of Islamic principles. This study is guided by two key research questions: (1) What are the compliance levels of vaccines with Brunei GD 24:2010 standard guidelines? And (2) What are the challenges hindering the production of halal vaccines? And to answer these questions, the study aims to (i) evaluate vaccine compliance with the GD 24:2010 standard guidelines and (ii) identify specific challenges in implementing halalan thayyiban principles in vaccine production.

The findings of this study are significant for integrating Islamic principles into modern healthcare. By examining the application of halalan thayyiban principles to vaccine production, this research contributes to fostering trust among Muslim consumers and enhancing public health initiatives. By examining vaccine patents, reviewing certification practices, and analysing production processes, this research seeks to provide insights for regulatory bodies, pharmaceutical manufacturers, and policymakers. Ultimately, it aims to

bridge the gap in halal vaccine production and certification processes, offering practical recommendations to align modern medical practices with Islamic principles.

## **2. Materials and methods**

This study utilises qualitative research design by using document analysis to explore compliance of vaccine production as outlined in Brunei “GD 24:2010 - Manufacturing & Handling of Halal Medicinal Products, Traditional Medicines & Health Supplements” standard guidelines. According to Creswell (2014), qualitative research is used when the objective is to explore and it is useful when dealing with complex documents such as patents. Thus, the qualitative approach allows an in-depth understanding of the *halalan thayyiban* in the concept of vaccines as it seeks to assess whether the production methods and ingredients described in patents align with halal principles and as outlined in Brunei's GD 24:2010 standard guidelines.

The study involved analysing patents, ingredient sourcing and production processes of four (4) types of vaccine, namely: inactivated vaccines (e.g., Hepatitis A), mRNA vaccines (e.g., Pfizer and Moderna COVID-19 vaccines), live-attenuated vaccines (MMR and chickenpox) and subunit/recombinant vaccines (Hepatitis B), to identify critical points of compliance or non-compliance with *halalan thayyiban* principles as outlined in Brunei's GD 24:2010 standard guidelines. These types of vaccines were chosen based on their relevance to common public concerns and availability of detailed production processes in public databases such as Google Patents. The study also uses thematic analysis by identifying the key themes such as ‘animal-derived ingredients’, ‘stabilisers’, ‘enzymes’, ‘synthetic’, etc. The data collected were from vaccine patents and literature where the information on the production processes, ingredients and manufacturing protocols of the four (4) types of vaccines was obtained from publicly available patents and scientific literature. The data were also collected from halal pharmaceutical standards such as Brunei GD 24:2010 standard guidelines where the guidelines served as primary reference for halal compliance criteria.

When developing vaccines that involve tissue culture, recombinants, or the need for multiplication of bacteria or viruses, the media materials being used must be analysed. The halal status of a product is generally determined by the raw materials being utilised, the manufacturing process, and the production facilities (Nadha, 2022). This is also known as halal critical control point (HCCP) which refers to identifying and monitoring any specified points in the operation, preparation and processing of halal products that could result in potential risks which could compromise the halal integrity. Therefore, the analysis of this study was guided by using HCCP framework where each vaccine types was evaluated for its compliance by using two key criteria which are; raw materials to identify halal or non-halal substances such as porcine-derived ingredients and alternative sources, and production processes to examine the manufacturing protocols to identify the risks of contamination. A conceptual framework based on Brunei GD 24:2010 standard guidelines (Figure 1) was also being used to classify vaccines as high compliant, partially compliant or low compliant.

## **3. Results and Discussion**

### **3.1 General Islamic Principles Pertaining to Pharmaceutical Products**

The origin of vaccinations is an important criterion for Muslim community in determining whether or not the vaccines are from permissible sources (Maizirwan and Ja'afar, 2009). It is clearly stated in the primary source of shariah law that consumption of dead meat, blood, flesh of swine, animals that are dedicated other than Allah are prohibited and classified as

*najs* for Muslims to consume except in *dharurah* (compelling necessity; emergency) situations. As stated in surah Al-Maidah Verse 3:

حُرِّمَتْ عَلَيْكُمْ أَلْمَيْتَةُ وَالْدَّمُ وَلَحْمُ الْخَنزِيرِ وَمَا أُهْلِيَ لِغَيْرِ اللَّهِ بِهِ وَالْمُنْخَنِقَةُ وَالْمَوْقُوذَةُ وَالْمُتَرَدِّيَةُ  
وَالنَّطِيحَةُ وَمَا أَكَلَ السَّبُعُ إِلَّا مَا ذَكَّيْتُمْ وَمَا ذُبِحَ عَلَى النُّصُبِ وَأَنْ تَسْتَقْسِمُوا بِالْأَزْلَمِ ذَلِكَمْ فِسْقٌ الْيَوْمَ  
يُنَسِّسُ الَّذِينَ كَفَرُوا مِنْ دِينِكُمْ فَلَا تَخْشَوْهُمْ وَاخْشَوْنِ الْيَوْمَ أَكْمَلْتُ لَكُمْ دِينَكُمْ وَأَتِمَمْتُ عَلَيْكُمْ نِعْمَتِي  
وَرَضِيتُ لَكُمُ الْإِسْلَامَ دِينًا فَمَنْ اضْطُرَّ فِي مَخْمَصَةٍ غَيْرِ مُتَجَانِفٍ لِإِثْمٍ فَإِنَّ اللَّهَ غَفُورٌ رَحِيمٌ

Translation: Prohibited to you are dead animals, blood, the flesh of swine, and that which has been dedicated to other than Allah, and [those animals] killed by strangling or by a violent blow or by a head-long fall or by the goring of horns, and those from which a wild animal has eaten, except what you [are able to] slaughter [before its death], and those which are sacrificed on stone altars, and [prohibited is] that you seek decision through divining arrows. That is grave disobedience. This day those who disbelieve have despaired of [defeating] your religion; so fear them not, but fear Me. This day I have perfected for you your religion and completed My favour upon you and have approved for you Islam as religion. But whoever is forced by severe hunger with no inclination to sin - then indeed, Allah is Forgiving and Merciful.

The above verse clearly states the things that are prohibited for Muslims, however if a person has no alternatives for it or to suppress its hunger, the prohibited things become permissible as long as the amount of consumption is enough to prevent death and the person has no inclination to sin. This principle of necessity does not only apply to food but also extends to vaccinations. A vaccine is permissible for Muslim's consumption even if the ingredients of the vaccine contain porcine-derivative or other impermissible substances. This is based on the concept of 'dire necessity renders the impermissible to be permissible'. However, the opinions of whether vaccination can be classified as a dire need varies among Islamic scholars as some scholars classify vaccination as a dire need while some considered them as otherwise due to the unguaranteed side effects in preventing and curing diseases.

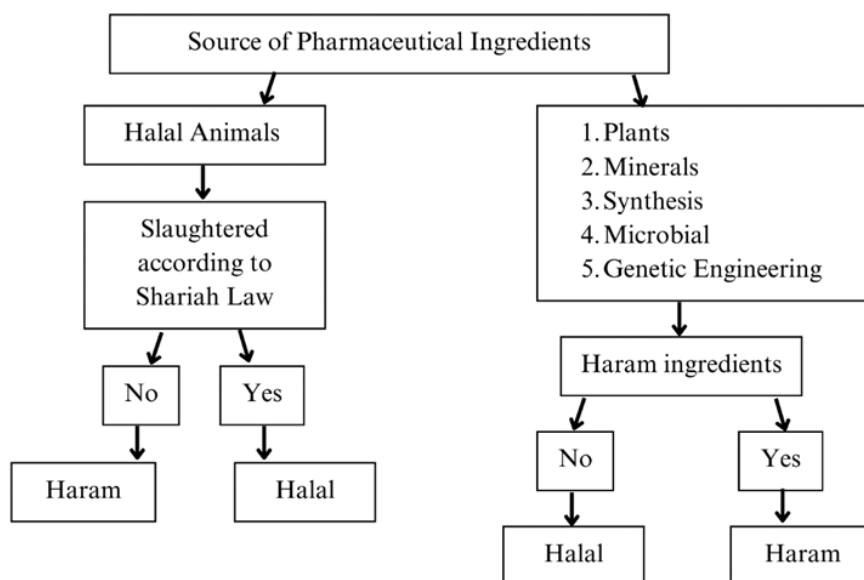
The concept of *istihalah* is also important in the production of vaccines. *Istihalah* is one of the principles that should be considered in deciding the status of a medicine that is mixed with non-halal substances (Wan Ismail, 2016). According to Sheikh al-Qaradawi (may Allah has mercy upon his soul), there are three requirements that must be fulfilled before using porcine products in medical treatment; (i) the medicine must be used in cases of emergency between life and death, (ii) the product must be recommended by knowledgeable and trustworthy Muslim physicians and (iii) no halal alternatives available. However, there are some debates on whether the concept of *istihalah* can be applied in medicinal products. One view is that *istihalah* can be applied in medicinal products such as vaccines. For instance, the Islamic Religious Council of Singapore in February 2012 has applied the *istihalah* concept in determining the use of rotavirus vaccine. The fatwa committee has decided that the percentage of porcine-derived enzymes in trypsin solution should be 0.0001% during the process of manufacturing of rotavirus vaccine. If the percentage is met, the trypsin solution is seen as pure as it has undergone the processes of dilution.

### 3.2 Vaccine Ingredients in Accordance to Brunei GD 24:2010 Standard Guidelines

Generally, the ingredients of vaccines may differ depending on the specific vaccine and its formulae. There are six main components in vaccines which are; active ingredients, adjuvants, stabilisers, preservatives, emulsifiers and other excipients, where each ingredient serves its own purpose (Gunay, 2023). Etiler (2018) states that active substances may include antigens, live viruses, inactivated viruses, purified viral proteins, inactivated bacterial toxins, or bacterium polysaccharides that can trigger the production of antibodies by the immune

system. Adjuvants are compounds used in combination with bacterial and viral components to improve a particular response to antigens (Garcon and Friede, 2018). It works to lengthen the time that cells are activated, which can fortify the immunological response. It also reduces the quantity of antigen per dosage.

Additionally, stabilisers are chemicals added to vaccinations to keep them stable until they are administered, protecting them from unfavourable circumstances. For example, sodium salts stabilise the pH level and maintain the quality of vaccination antigens by reducing the acidity of the product. Preservations on the other hand are substances that destroy fungus and bacteria. They stop the growth of microorganisms in vaccinations. Emulsifiers are employed to guarantee uniform distribution of the vaccine's active components. The final elements in vaccines are other excipients/adjuvants. Other adjuvants, such as antibiotics, may also be included in vaccines to stop bacterial contamination during production. Consequently, substances employed in the production of the vaccine can be found in the finished product. Formaldehyde, for instance, is frequently employed for inactivation in the production of vaccines for both humans and animals. However, according to the Centre of Biologics Evaluation and Research (2023), the final product has very low quantities of formaldehyde, which does not eliminate the safety problem.



**Fig. 2:** Sources of Pharmaceutical Ingredients  
**Source:** Slamet (2017)

According to a study by Slamet (2017), the source of medicinal ingredients comes from animals and also from other materials such as plants, minerals, synthesis, microbial and genetic engineering. Figure 2 illustrates the sources of pharmaceutical ingredients. Vaccines derived from animals slaughtered according to shariah law are considered as halal while those from non-halal sources are deemed as haram. The halal status of vaccines centres on various critical points in their production particularly the source of ingredients, medium used for cultivation and the potential of cross-contamination during manufacturing. Halal violations may occur if the HCCP is not carefully monitored. In ensuring that vaccines meet halal standards, it requires a thorough examination and assessment of every stage of production, from raw materials to the final product. This process necessitates the involvement of skilled personnel who are well-versed in both Islamic jurisprudence and the technical aspects of vaccine manufacturing.



Each ingredient used in vaccine productions originates from various sources, including animals, plants, microbial and synthetic origins. A detailed analysis of these origins is crucial to evaluate their permissibility under shariah law. According to the PBD 24:2007 (Brunei Darussalam Halal Food Standard), there are three sources of ingredients that are permissible which are animals, plants and microbial and synthetic ingredients. The guidelines mandates that all ingredients in halal-certified products must be sourced from halal origins, emphasising on the aspects of transparency, safety and pureness in pharmaceutical ingredients. For animal-derived ingredients, certain vaccines may contain ingredients derived from animal sources as long as it is not prohibited in Islam and does not cause harm to human beings. According to Brunei GD 24:2010, any animal derived components must be from animals that are slaughtered according to shariah law. Therefore, ingredients sourced from non-halal animals such as porcine derivatives or animals that are not slaughtered according to shariah law are strictly prohibited.

According to Brunei GD 24:2010, plant and microbial-derived ingredients are generally permissible. For instance, yeast or bacterial cultures are generally permissible in Islam, however, further analysis is required to ensure no cross-contamination occurs during cultivation and extraction. Synthetic ingredients such as those that are produced via chemical synthesis offer an alternative to animal-based ingredients. According to Brunei GD 24:2010, synthetic ingredients are often derived from non-animal sources and are generally permissible. These ingredients offer potential compliance with halal requirements as long as they are not contaminated during production.

### 3.3 Analysis of Vaccine Patents

The study evaluated vaccine compliance with halalan thayyiban principles as outlined in Brunei GD 24:2010 standard guidelines that focuses on ingredient sourcing and production and manufacturing processes. Results show three (3) key findings which are compliance levels of vaccine types, HCCP and barriers to effective certification.

The findings of this study reveal varying levels of compliance among the four (4) types of vaccines (inactivated, mRNA, live-attenuated and subunit/recombinant vaccines) with halalan thayyiban principles as outlined in Brunei GD 24:2010 standard guidelines. For inactivated vaccines such as Hepatitis A and flu shot, these types of vaccine were found to have the lowest compliance with halalan thayyiban concept. This is because the production process for inactivated vaccines often uses chemicals such as formaldehyde to kill the virus. Moreover, it uses porcine-derived ingredients or known as trypsin, the use of proteins and stabilisers that might be derived from animal sources. Concerns raised due to the use of stabilisers as there was an indication of bovine serum being used although in limited quantities. The use of bovine ingredients can be deemed as non-halal unless they are verified and sourced from halal slaughtered animals. This raises concerns among Muslim consumers and poses a significant compliance challenge. Therefore, there is a need to necessitate substitution of porcine-derived enzymes with halal certified alternatives such as plant-based or synthetic enzymes to fully achieve compliance.

mRNA vaccines such as Moderna and Pfizer BioNTech COVID-19 vaccines show a partial compliance with halalan thayyiban concept. Their production primarily involved synthetic and biochemically engineered components. These vaccines represent a novel approach that uses mRNA technology encoding for viral proteins to trigger an immune response without using live virus components. The primary concerns with mRNA vaccines

is the sourcing of raw materials and the production processes that involve in the creation of lipid nanoparticles that are being used to deliver the mRNA. Although mRNA vaccines are becoming popular in the recent pandemic response, it raises questions on the halal compliance due to the production processes and additives being used. Pfizer-BioNTech and Moderna vaccines use synthetic mRNA encased in lipid nanoparticles. Although mRNA does not present any halal concerns, the lipid nanoparticles may include ingredients derived from animal sources. These lipid nanoparticles are crucial for delivering the mRNA into human cells. Moreover, the analysis of ingredients list does not indicate any direct use of porcine products, however, the sourcing of lipids lacks halal certification or clarification.

Live-attenuated vaccines such as chickenpox and MMR (measles, mumps and rubella) presented a notable compliance issue. These vaccines often contain weakened forms of virus to stimulate immunity. These vaccines provide strong, long-lasting immune responses, however, it may present more complex challenges due to the usage of animal cells as growth media such as foetal bovine serum for culturing viruses. The production of live-attenuated vaccines typically involved cultivating the virus in animal cell culture. For instance, MMR vaccine is known to use chicken embryo fibroblast cells which are generally accepted in shariah law. However, concerns arise when animal-derived enzymes such as trypsin which are typically from porcine sources being used in the production process. Additionally, the risk of cross-contamination during production processes further complicates their compliance.

The last type of vaccines is the subunit or recombinant vaccine. This category of vaccines demonstrates a spectrum of compliance. For instance, Hepatitis B vaccine exhibited a high potential of compliance as it utilises recombinant technology. Moreover, they rely on genetically engineered yeast cells rather than animal-derived ingredients. However, stabilisers and preservatives such as polysaccharides may be derived from animal sources, might require ingredient modification especially for components derived from non-halal sources in order to achieve full compliance and meet the requirements of Brunei GD 24:2010 guidelines. Table 1 shows the overview of the raw materials and manufacturing processes of the four (4) types of vaccines.

**Table 1:** Overview of Vaccine Types, Raw Material and Manufacturing Processes

Vaccine Types	Examples	Raw Materials	Manufacturing Processes
Inactivated Vaccines	Hepatitis A	Trypsin; Aluminium Hydroxide; Saponin	Chromatography
	Flu Shot	Animal cell culture from chicken embryo	Animal cell culture by using MDCK cell
mRNA Vaccines	COVID-19	Lipids; Additives	Controlled lab environment; mRNA produced synthetically
Live-attenuated vaccines	Chickenpox	Sucrose; Hydrolysed Gelatine; Foetal Bovine Serum	Virus propagation; Sonification
	MMR	Chicken embryo; Trypsin	Incubation
Subunit, Recombinant Vaccines	Hepatitis B	Yeast; Aluminium Salts, Amino Acids, Sodium Chloride	Genetically engineered

The analysis of halal critical control point (HCCP) focused on three (3) essential areas which are; raw materials, production processes and certification process. These areas were identified as pivotal in determining whether vaccines meet halalan thayyiban requirements as outlined in Brunei GD 24:2010 standard guidelines.

One of the most critical barriers to compliance is the sourcing of ingredients. Most vaccines utilise non-halal ingredients such as porcine-derived trypsin or foetal bovine serum during the production processes. For instance, inactivated vaccines commonly used porcine trypsin and live-attenuated vaccines use foetal bovine serum as a growth medium. These ingredients are considered to be non-halal and contradicts with Islamic principles. Furthermore, the lack of readily available halal certified alternatives further complicates in achieving full compliance.

The second area is on the production processes. The production processes of vaccines often present significant risks of cross-contamination particularly in facilities that handle both halal and non-halal substances. Segregation is important to ensure that halal vaccines are not contaminated during production, processing, packaging and storage. Thus, it is important to implement rigorous standard operating procedures (SOPs) for cleaning, segregation and monitoring at every stage of production to maintain halal integrity. Additionally, manufacturing facilities should be certified as halal especially for manufacturers that aim to produce halal vaccines.

The last area is on the certification process. The halal certification process poses challenges that could potentially impact the approval of halal vaccines. Halal certification often involved rigorous procedures such as intensive documentation, inspections and verifications for all raw materials, production processes and facilities. These lengthy processes can delay the distribution of halal vaccines especially during public health emergencies such as the COVID-19 outbreaks. Additionally, the absence of a standardized halal certification framework across Islamic countries further complicates the process as manufacturers have to navigate varying standards and guidelines requirements which can cause confusion on which guidelines to follow.

### **3.4 Halal Vaccine Compliance**

Findings from the document analysis shows that, some vaccines could be modified to achieve a greater alignment with Brunei GD 24:2010 standard guidelines. For mRNA vaccines, the vaccines can be certified as halal by ensuring that the lipid sources are certified halal. Live-attenuated vaccines on the other hand are generally free from non-halal ingredients in the final production stage. However, the production process may conflict with halal principles. Compliance can be enhanced by using halal-certified alternatives for any animal-derived enzymes and ensuring segregation of production lines to prevent cross-contamination from occurring. Overall, mRNA and live-attenuated vaccines show the potential for compliance if ingredient sources are verified and facilities are free from contamination.

Inactivated vaccines on the other hand shows that the vaccines has a low compliance with Brunei GD 24:2010 standard guidelines due to the vaccines utilizes porcine-derived enzymes or trypsin during the production processes. Compliance can be enhanced by using halal-certified alternatives during the production processes. In contrast, subunit and recombinant vaccines are generally compliant with halalan thayyiban principles due to the ingredients being used are mostly genetically engineered. However, all additives used must



be verified as halal to ensure full compliance. Table 2 shows the compliance level within Brunei GD 24:2010 standard guidelines.

**Table 2:** Vaccine Types and Compliance Level within Brunei GD 24:2010 Guidelines

Vaccine Types	Examples	Compliance Level	Challenges Identified
Inactivated Vaccines	Hepatitis A, Flu Shot	Low Compliance	Use of porcine enzymes during production.
mRNA Vaccines	Moderna, Pfizer	Partial Compliance	Synthetic stabilisers of uncertain origin.
Live-attenuated	Chickenpox, MMR	Partial Compliance	Cross-contamination risks.
Subunit/Recombinant Vaccines	Hepatitis B	High Compliance	Lengthy halal certification process.

### 3.5 Challenges in Achieving Vaccine Compliance with Brunei GD 24:2010 Standard Guidelines

There are certain types of vaccines that were found to be a barrier to halal compliance due to the usage of animal-derived stabilisers. For instance, inactivated vaccines. These vaccines often use ingredients that are derived from animal sources which may not meet the requirements outlined in Brunei GD 24:2010 standard guidelines due to the concerns if the animals used as ingredients are from halal animals and are slaughtered according to Islamic law. Moreover, the use of bovine-derived materials and certified ingredients and materials present a conflict within the halalan thayyiban principles. Until the ingredients and materials are certified as halal, the status of the products may still remain doubtful. An alternative approach is to use non-animal stabilisers that can mitigate compliance issues and promote the development of fully halal-compliant vaccines.

Findings from the analyses being conducted revealed that there are three main challenges in order to achieve full compliance of halal vaccines which are: (i) supply chain, (ii) certification limitation and (iii) global regulatory variations. The first challenge is the supply chain. Ingredients are very important in sourcing the products that are halal or non-halal. Sourcing halal certified ingredients for vaccines is often hindered by a lack of transparency in the supply chain. From the analysis of the vaccines patents, it was found that the ingredients are not specifically mentioned if the vaccines uses halal animal-derived ingredients. Thus, the reliance on intermediates in the procurement process can obscure the origin of ingredients. This makes it difficult to verify the halal status of the ingredients being used.

Second is the certification limitations. With the current advancement in technologies, the current halal certification processes may not be fully adapted to accommodate the advanced vaccine technologies such as mRNA and recombinant vaccines. The gap suggests a need for an updated halal standards specifically for pharmaceutical products with clear guidelines on new vaccine technologies. Third is the global regulatory variations. The variation in halal standards across Islamic countries poses a challenge for manufacturers that aim to distribute vaccines globally. The absence of unified halal standards for pharmaceuticals complicates the compliance for companies that are looking to serve the Muslim populations in multiple regions.

Therefore, this challenge underscores the importance of sourcing transparency and the need for closer collaboration from varieties of government authorities such as between vaccine manufacturers, Islamic scholars and halal certification bodies. Halal certification bodies could also work closely with international health organisations such as WHO in order to develop unified standards that support compliance across different regions. Additionally, integrating halal certification with GMP could enhance confidence in the halal status of vaccines which helps in ensuring it meets both safety and religious requirements.

### **3.6 Opportunities in Achieving Vaccine Compliance with Brunei GD 24:2010 Standard Guidelines**

While there are certain types of vaccines that pose a challenge for compliance, there are also certain types of vaccines that present fewer halal compliance challenges such as subunit and recombinant vaccines. These vaccines generally use genetically engineered proteins such as yeast, thus reduces the need for animal-derived ingredients in their formulations. However, stabilisers and preservatives being used in these vaccines may be derived from animal sources or unknown sources, which may complicate compliance for achieving full compliance on halal certification.

Moreover, findings indicate that mRNA and live-attenuated vaccines exhibit significant potential for compliance. This is because mRNA vaccines avoid the use of live viruses, thus reducing concerns on animal-derived ingredients. However, the lipid nanoparticles used for mRNA delivery may pose a challenge as the sources may be from animal origin. Despite that, these vaccines have the potential to be accepted within Muslim communities if manufacturers ensure that all excipients and additives are halal-certified. This is because the production process aligns more closely with halal standards. To enhance full compliance, manufacturers could collaborate with halal certification bodies to ensure comprehensive documentation and transparency of all ingredients sources including stabilisers and preservatives.

Therefore, in this modern society, the use of biotechnology is very much needed to develop halal certified ingredients to reduce reliance on the non-halal components. This can be done with global collaboration such as partnering with halal certification bodies and Islamic councils worldwide to promote standardisation on halal certified vaccines. For instance, adopting the Brunei GD 24:2010 standard guidelines as a model for global halal pharmaceutical standards which can help to enhance the consistency in compliance standards. Additionally it could help in encouraging the vaccine manufacturers to invest in halal vaccines, thus increasing the demand for halal pharmaceuticals globally.

### **Conclusion**

As the global demand for halal certified products continues to rise, this research emphasises on the importance of aligning vaccine production processes with halal *thayyiban* principles. This research has provided a comprehensive analysis of vaccine compliance with Brunei's GD 24:2010 standard guidelines. By evaluating the halal critical control point such as ingredients sourcing and production processes, this research has highlighted the challenges and opportunities in ensuring vaccines meet the requirements for halal certification without compromising their efficacy and safety. One of the key challenges is the ingredient sourcing as many vaccines continue to rely on non-halal substances such as trypsin or foetal bovine serum. This research also emphasises the risks of cross-contamination in facilities handling both halal and non-halal products. Thus, the findings emphasise the importance of greater transparency in the sourcing and production processes of vaccines,

alongside the potential of replacing non-halal ingredients with halal alternatives such as plant-based or synthetic components. These innovations not only align with Islamic ethical standards but also address the growing global demand for halal-certified pharmaceuticals products.

Despite these challenges, the research also identifies significant opportunities for progress. The advancement of biotechnology offers potential in developing halal- certified alternatives such as plant-based or synthetic stabilisers that can replace the non-halal components. Vaccines such as mRNA and subunit recombinant vaccines demonstrate a potential for compliance due to their reduced reliance on animal-derived ingredients. However, further innovations are required to ensure excipients and other additives used meet the requirements of Brunei's GD 24:2010 standard guidelines.

Additionally, the importance of collaboration between religious scholars such as scientists and policymakers are essential in bridging the gaps in understanding, fostering trust within Muslim communities and ensuring the vaccines are widely accepted. This research contributes to the growing knowledge of halal pharmaceuticals and laying a foundation for future studies in this field. While significant progress has been achieved, considerable challenges still remain in bridging the gap between Islamic law and modern scientific practices. By emphasising the need for collaboration and innovative approaches, this research aims to foster the development of a more inclusive and ethically aligned framework for halal-certified vaccine production.

Ultimately, the journey towards achieving halal-certified vaccines is not just merely scientific but also morally imperative as it reflects a commitment to harmonising faith and science in ways that can benefit human beings while respecting the diverse values and beliefs and upholding the ethical standards central to Islamic teachings. Achieving this balance will not only strengthen public health systems but also reaffirm the importance of religious values in the field of scientific innovation.

## References

- Al-Quran Al-Karim
- Brunei Darussalam Medicines Control Authority. (2010). GD 24:2010 Guidelines of Halal Medicinal Products.
- Common ingredients in FDA-Approved vaccines*. (n.d). Food and Drugs Administration (FDA). Retrieved October 10, 2024, from <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-fda-approved-vaccines>
- El-Muhammady, S., Ahmad, S., & Syed, S. (2023). Balancing Religious Compliance and Scientific Efficacy in Vaccine Production. *Vaccine Research & Development*, 10(2), 112-123.
- Ernawati, E. (2019). The Global Competitiveness Study of Halal Pharmaceuticals and Cosmetics Industry. *Mega Aktiva: Jurnal Ekonomi dan Manajemen*, 8(1), 51-61.
- Fatwa (Legal) Committee Islamic Religious Council of Singapore. Fatwa Issued [online]. Majlis Ugama Islam Singapura. 2013. Available from: [http://www.muis.gov.sg/officeofthemufti/Fatwa/rotavirus\\_vaccine.html](http://www.muis.gov.sg/officeofthemufti/Fatwa/rotavirus_vaccine.html): Accessed 2024 Sept 7
- GÜNAY, H. M. (2023). The Role Of Istihalah (Transformation) And Istihlak (Consumption) In The Permissibility of Vaccines Derived From Forbidden Origins: An Islamic Law Perspective. *Journal of Halal and Ethical Research*. <https://doi.org/10.51973/head.1338259>
- Ismail WRBW, Othman M, Rahman RA, Kamarulzaman NH, Rahman SA. Halal Malaysia Logo or Brand: The Hidden Gap. *Procedia Econ Financ*. 2016; 37:254–61.

- Jabbar, A., Ali, F., & Ahmed, S. (2020). Global Variations in Halal Standards: Implications for Vaccine Certification. *Journal of Global Health*, 22(4), 145-156
- Karim, M., & Akhtar, S. (2023). Ensuring Halal Compliance in Pharmaceutical Production. *Pharmaceutical Manufacturing & Processing*, 17(1), 56-67.
- Meo, S. A., Bukhari, I. A., Akram, J., & Klonoff, D. C. (2021). COVID-19 vaccines: Comparison of Pfizer/BioNTech and Moderna vaccines. *European Review for Medical and Pharmacological Sciences*, 25(3), 1663–1679.
- Mujahid, N., Kahn, M., & Akbar, M. (2021). Certification Processes for Halal Pharmaceuticals: Challenges and Opportunities. *International Journal of Health Management*, 13(1), 77-89.
- Nadha, C. (2022, August 20). *Getting To Know Vaccine Manufacturing And Its Halal Critical Point | LPPOM MUI*. LPPOM MUI. <https://halalmui.org/en/recognize-vaccine-making-and-critical-point-halal/>
- Ozawa, S., Mirelman, A., Stack, M. L., Walker, D. G., & Levine, O. S. (2012). Cost-effectiveness and economic benefits of vaccines in low- and middle-income countries: a systematic review. *Vaccine*, 31(1), 96–108.
- Padela AI, Furber SW, Kholwadia MA, Moosa E. Dire necessity and transformation: entry-points for modern science in Islamic bioethical assessment of porcine products in vaccines. *Bioethics*. 2014;28(2):59–66. doi:10.1111/bioe.12016.
- United Nations. (2019). World Population Prospects 2019: Ten Key Findings. Retrieved from <https://population.un.org>
- World Health Organization: WHO. (2020, December 8). *How are vaccines developed?*. Retrieved from <https://www.who.int/newsroom/feature-stories/detail/how-are-vacines-developed>