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Identification of halal labels on primary and secondary drug packaging at RSUD Dr. Soegiri Lamongan

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ABSTRACT

The majority of religions practiced by residents in the Lamongan area are Islam. In Islam, it is commanded to seek treatment with what is halal and is prohibited from seeking treatment with what is haram. Consumers cannot meet the manufacturer directly, but they must pay attention to the halal label on the drug packaging to consider their choices. This study aims to determine the percentage of drugs with the halal logo at Dr Soegiri Lamongan. This research used an observational design with samples of oral medication packaging at Dr. RSUD. Soegiri Lamongan and use a purposive sampling technique. The instrument used is an observation sheet. The research results showed that from 395 items of oral drugs at RSUD Dr Soegiri Lamongan had a halal label 97 (25%) consisting of capsule preparations of 12 (22%) medicinal items, caplets 6 (12%) medicinal items, tablets 65 (27%) medicinal items, dry syrup 1 (10%) items of medicine, suspension 4 (40%) items of medicine, elixir 1 (100%) items of medicine, drops 2 (25%) items of medicine, and syrup 6 (35%) items of medicine. In contrast, those that do not have a halal label are 298 (75%) oral drugs. The McNemar Test results showed a value of $p = 0.000$ with a significance value of $p < 0.05$ for all drugs and oral solid drugs. Meanwhile, the results of the McNemar test on oral liquid drugs show a value of $p = 1.000$ with a significance value of $p > 0.05$. Thus, many oral drugs still do not have a halal label on their packaging. Thus, many oral drugs still do not have a halal label on their packaging. However, these drugs are not necessarily haram. The certification process takes quite a long time, and the critical points for halal medicine, which lie in the ingredients, processing, packaging, and storage, are important things in the halal certification process to obtain a halal medicine label.

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Keywords
Critical points, Drug, Halal label, Packaging.

INTRODUCTION

Lamongan is one of the cities in East Java Province, and most of its population is Muslim (Abadi et al., 2020). Based on population data according to sub-district and religion adopted in Lamongan Regency, as many as 1,172,320 people in 2018 adhere to Islam, and in 2022, it will increase to 1,455,675 people (BPS Kab. Lamongan, 2018). Halal is a condition especially free from prohibited elements and is permitted to be used and consumed by Muslim consumers according to Islamic law (Rohim & Priyatno, 2021). Halal in a product is related to food and medicines (Kemsetneg RI, 2014).

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The use of Halal drugs will be very beneficial for every user physically and mentally. A drug has halal status if it is declared free from the halal critical point and has a halal certificate (Asmuni et al., 2020). A halal certificate issued by the MUI must include a halal label on product packaging (Faridah, 2019). The Muslim community needs guarantees of security, comfort, protection, and legal certainty regarding the halalness of products consumed, used, or utilized. Fulfilling halal living needs is the obligation of every Muslim because this is not only related to religious beliefs but also health aspects (Warto & Samsuri, 2020). "From Abu Darda', he said: Rasulullah SAW said: Indeed, Allah has sent down disease and a cure for every disease, so seek treatment and do not seek treatment with what is haram." (HR. Abu Dawud). From this hadith, it is known that Allah SWT has forbidden His servants to seek cures with haram things but has ordered them to seek treatment with halal things (Trisnawati & Kusuma, 2017). A study conducted by Aziz et al. (2014) stated that most medicines on the market do not have a halal logo, and only 11.4% of 132 respiratory pharmaceutical products in Malaysian hospitals have been declared halal. According to research conducted at RSI Sultan Agung Semarang by Meilani et al. (2022), only 21% of 125 tablet medicines included a halal label on the packaging.

Drugs must be halal certified and further regulated in Article 2 paragraph (2) of the Republic of Indonesia Government Regulation 39 of 2021 concerning implementing Halal Product Guarantees. According to the Government Regulation of the Republic of Indonesia Number 39 of 2021 concerning the Implementation of Halal Product Guarantee Article 141, paragraph (1) explains that there are stages in the obligation to be certified halal for drugs with a period of up to 2026 for traditional drugs, quasi-drugs and health supplements, until 2029 for over-the-counter drugs and limited over-the-counter drugs, and until 2034 for hard drugs excluding psychotropics (Kemsetneg RI, 2021). Often, consumers cannot meet the manufacturer directly, but they must pay attention to the halal label listed on the drug packaging to consider their choices (Gita & Sulistyowati, 2020). Packaging is a container or wrapper used for an item to make it safe, attractive, and appealing to consumers, protect the product from damage, and guarantee consumer satisfaction (Mukhtar & Nurif, 2015). Public perception of halal drug certification is improving (Utami & Nurkhasanah, 2021). So, more and more people need a guarantee of halal drugs.

Based on the background explained above, it is necessary to carry out research regarding the identification of halal labels on the primary and secondary packaging of medicines located at RSUD Dr. Soegiri Lamongan to find out the number of halal medicines that have halal labels on their primary and secondary packaging. A halal label on drug packaging can make patients more legally assured regarding the safety and comfort of consuming medicine. This research aims to determine the percentage of oral drugs with the halal logo at RSUD Dr. Soegiri Lamongan.

RESEARCH METHOD

Materials

The material used in this research was an observation sheet and the statistical package for the social sciences (SPSS). The observation sheet contains the name of the drug, the form of the drug, the manufacturer, the packaging (primary and secondary), and the halal label (yes and no). The samples that the researchers used were all types of oral drugs available at RSUD Dr. Soegiri Lamongan or 395 oral drugs consisting of 54 capsules, 49 caplets, 239 tablets,4 powder, 17 syrups, 10 suspensions, 1 elixir, 8 drops, 10 dry syrups, and 3 emulsions. Oral drugs were chosen because this type of drug is the most commonly used and is often obtained by the public. Statistical Package for the Social Sciences (SPSS) analyses the differences between primary and secondary packaging.

Methods

This research uses a descriptive observational research design. Researchers observed all oral drug items at the pharmacy installation of RSUD. Dr. Soegiri Lamongan used an observation sheet to record the name of the drug, the form of the drug, the manufacturer, and the location of the halal label on the packaging. Then, a statistical test (SPSS) was carried out using the McNemar test to analyze the differences in halal labels on primary and secondary packaging with the parameter that there was a difference if the p-value < 0.05 and no difference if the p-value > 0.05. The method used in this research is direct observation using an observation sheet. The research stages carried out are shown in Figure 1.

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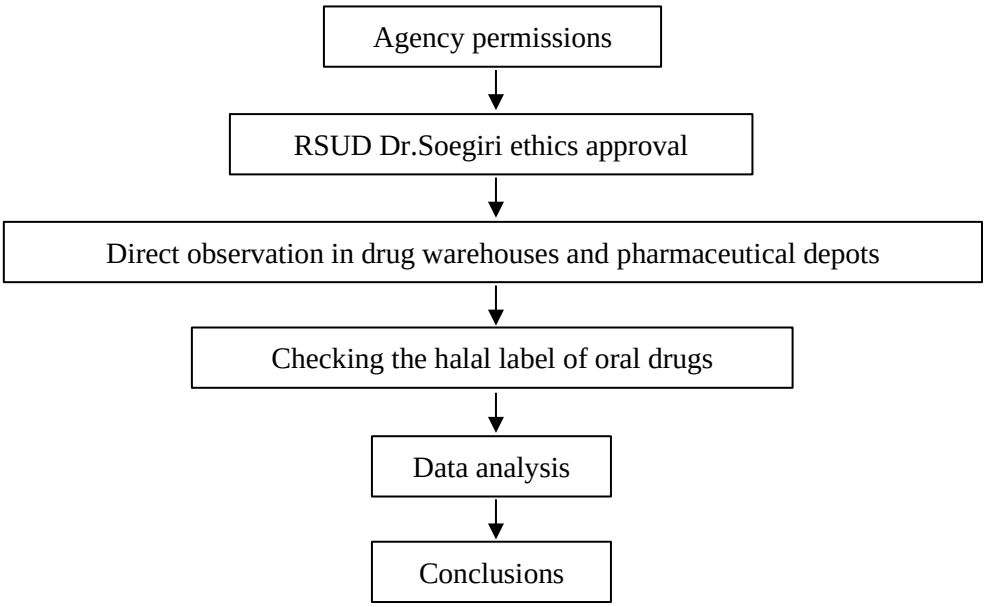

Figure 1. Flow chart of the research stages.

Data analysis

This study uses a direct observation method on the research object of oral drug packaging and univariate analysis to describe data from the identification of halal labels on primary and secondary packaging of oral drugs in the form of percentages presented in a table or graphic (Senjaya et al., 2022). The investigation was carried out by calculating the percentage (%) of oral drugs that have a halal label and do not have a halal label on their primary or secondary packaging, both in general (as a whole) and in detail (each drug dosage form) using the percentage calculation formula. Moreover, analyzed with the McNemar statistical test.

RESULT AND DISCUSSION

Based on the research in Table 1 shows that the number of oral drugs that have a halal label on the primary and/or secondary packaging is less than 97 drug items (25%). The number of oral drugs that do not have a halal label on the primary and/or secondary packaging is more than 298 drug items (75%).

Table 1. Calculation results of the percentage of oral drugs that have a halal label and do not have a halal label.

No.	Halal Label	Percentage	
		Quantity	%
1	Yes	97	25
2	No	298	75
	Total	395	100

Based on Figure 2, it is known that of the five forms of oral solid drugs that have the highest number of halal labels on primary and/or secondary packaging, tablets are (27%) and oral solid drugs that do not have halal labels on primary and/or secondary packaging is powder (0%). Based on Figure 3, it is known that of the five forms of oral liquid drugs that have the highest number of halal labels on the primary and/or secondary packaging are syrups with (35%) and oral liquid drugs that do not have halal labels on the primary and/or secondary packaging is emulsion (0%). The research results show that not all oral medicines at RSUD, such as Dr Soegiri Lamongan, have halal labels on their packaging. Medicinal items that do not yet have a halal logo are still doubtful about their halal status. The literature

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obtained explains that a product that does not have a logo on the packaging is not necessarily haram (Astuti et al., 2020). In addition, the halal certification process for medicinal products takes quite a long time, so including a halal label can be hampered. Products must comply with the Halal Guarantee System (SJH) criteria to obtain a halal certificate. Medicinal products that do not yet have the halal logo can sold because many people need them, provided they are used correctly. Even products that contain active ingredients or other additives that are not permitted can still be used if they can be used in emergencies and are limited according to their levels or needs; dangerous conditions (dharma) must be prevented wherever possible. Hazardous conditions (*dharar*) must be eliminated (MUI, 2013).

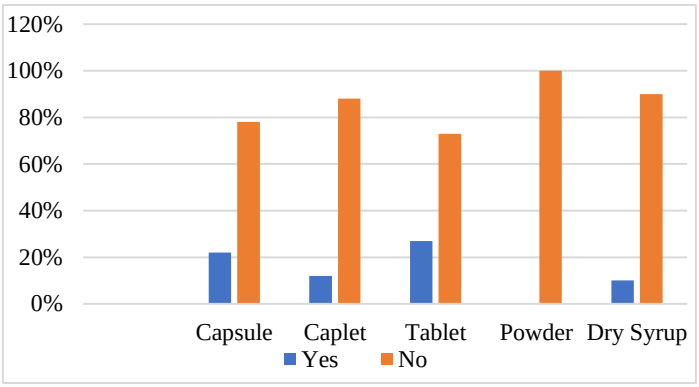

Figure 2. Percentage of halal labels for oral solid drugs.

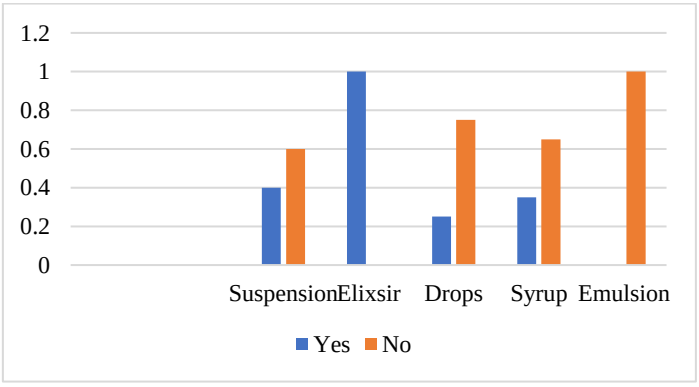

Figure 3. Percentage of halal labels for oral liquid drugs.

The critical point of drug halalness is also a consideration in obtaining a halal label. Several essential points for halal oral solid dosage forms that need to be considered include solvents, sweeteners, non-stick tablets, adsorbents, coloring agents, binders, flavoring agents, fillers, coating agents, disintegrating agents, hardeners, and lubricants. Materials for making tablets that need to be considered at the critical halal point are gelatin, cellulose acetate, alcohol, sucrose, magnesium stearate, lactose, and stearic acid because these materials are still halal in doubt (Jaswir et al., 2020). The critical point for halal capsules lies in the material from which the capsule shell is made, namely gelatin. The type of gelatin source determines the halal status of gelatin. Based on the Reference List of ingredients that have halal critical points and substitutions for non-halal ingredients explains that sweeteners that are critical points for halal oral liquid medicines are types of artificial sweeteners that are sourced from the amino acids aspartame and phenylalanine, such as aspartame. Antioxidant ingredients from chemical synthesis. Other ingredients that have a critical point for the halalness of oral liquid drugs, such as flavors, stabilizers, emulsifiers, colorants, and emulsifiers from the source of the ingredients, the process to the result must be free from the critical point (Jaswir et al., 2020). The research results on halal labels for oral medicines based on primary and secondary packaging are listed in Table 2.

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Table 2. Percentage of oral medicines labeled halal based on primary and secondary packaging.

No.	Oral Drug Packaging	Percentage		p-Value
		Quantity	%	
1	Primary	81	84	0.000
2	Secondary	96	99	
3	Primary & Secondary	80	82	

McNemar Test

Table 3. Percentage of oral solid preparations labeled halal based on primary and secondary packaging.

No.	Drug Form	Drug Packaging			Quantity of Halal Label	Percentage (%)			p-Value
		Primary	Secondary	Primary & Secondary		Primary	Secondary	Primary & Secondary	
1	Suspension	4	4	4	4	100	100	100	1.000
2	Elixsir	1	1	1	1	100	100	100	
3	Drops	2	2	2	2	100	100	100	
4	Syrup	6	5	5	6	100	83	83	
5	Emulsion	0	0	0	0	0	0	0	

McNemar Test

Table 4. Percentage of oral liquid preparations labeled halal based on primary and secondary packaging.

No.	Drug Form	Drug Packaging			Quantity of Halal Label	Percentage (%)			p-Value
		Primary	Secondary	Primary & Secondary		Primary	Secondary	Primary & Secondary	
1	Suspension	4	4	4	4	100	100	100	1.000
2	Elixsir	1	1	1	1	100	100	100	
3	Drops	2	2	2	2	100	100	100	
4	Syrup	6	5	5	6	100	83	83	
5	Emulsion	0	0	0	0	0	0	0	

McNemar Test

Based on Table 3 shows that the solid preparations that contain the most halal labels on primary packaging are caplets and dry syrup (100%). In comparison, the ones with the least halal labels on primary packaging are capsule preparations (58%). Likewise, most preparations that include the halal label on primary and secondary packaging are caplets and dry syrup (100%), while the least is capsule preparations (58%). The secondary packaging shows that all secondary packaging for oral solid preparations includes a halal label (100%). Table 4 shows that all oral liquid preparations have a halal label on either the primary or secondary packaging or both packages (100%), except for syrup preparations, which contain a halal label with a percentage of 83% on the secondary packaging.

The results show that not all halal labels on oral drugs are listed on the primary packaging and secondary packaging. Including a halal label on product packaging is important because the initial impression when a patient receives non-concocted medicine is the packaging. The inclusion of a halal logo on the primary packaging as a guarantee that the drug has halal status is essential because consumers can use the halal logo on the packaging as a guide for choosing and purchasing medicinal products (Kusumaningtyas & Prasetyo, 2022). Drug packaging must come from halal materials and be produced halal. Paper packaging often uses enzymes from other animals, which are microbial products whose halalness depends on the growth medium. Microbial growth media materials can come from pigs, taken from the meat, and enzymes in the meat, pancreas, and pork stomach (Jaswir et al., 2020). Packaging made from plastic has a critical point of halalness, which lies in the additional ingredients in the formulation. The packaging process has the potential for physical contamination by workers, such as hands, hair, and clothing (Habibah & Juwitaningtyas, 2022).

Apart from being influenced by the critical point of halal drugs, oral drugs that do not yet have a halal logo on their packaging may be due to the halal certification of the pharmaceutical industry, which

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is considered slow due to the structure of the pharmaceutical industry in Indonesia which is not yet optimal because the source of the ingredients used to make up the drugs is still 95% derived from abroad, namely China, India, America, and Europe (Nadha, 2022). Countries that export raw materials for drugs to Indonesia are mostly non-Muslim countries, which are less concerned with the halal status of drugs (Hudaefi et al., 2021). This pharmaceutical industry must also guarantee that each facility is free from haram elements or separate facilities between haram and halal (Ramadan et al., 2024).

The results of the McNemar test showed p value = 0.000 with a significance value of $p < 0.05$ for both the overall analysis results for oral drugs and oral solid drugs, which means there is a significant difference between the amount of halal labeling for oral drugs in primary packaging and secondary packaging. Meanwhile, the results of the McNemar test for oral liquid drugs showed p value = 1.000 with a significance value of $p > 0.05$, which means there is no significant difference between the amount of halal labeling for oral liquid medicines in primary packaging and secondary packaging.

CONCLUSION

Based on the research results, 395 items of oral medication have been labeled halal, 97 (25%), and of those that do not have a halal label, 298 (75%) oral drugs. Thus, there are still many oral drugs that do not have a halal label on their packaging. Drugs that do not have a halal label are not necessarily haram. The critical point of halal medicinal ingredients is crucial in the halal certification process to obtain a halal drug label.

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