Jurnal Farmasi Galenika (*Galenika Journal of Pharmacy*) (e-Journal) 2025; 11 (2): 136 – 147
ISSN: 2442-8744 (electronic); 2442-7284 (printed)
Journal Homepage: https://bestjournal.untad.ac.id/index.php/Galenika
DOI: 10.22487/j24428744.2025.v11.i2.16568

Pharmaceutical Compatibility of Non-Sterile Mixing Recipes in Pediatric Patients in Covid-19 Pandemic

(*Kesesuaian Farmaseutik Resep Racikan Non-Steril Pada Pasien Pediatri dalam Pandemi Covid-19*)

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Article Info:
Received: 25 September 2023
in revised form: 18 October 2023
Accepted: 30 October 2025
Available Online: 31 October 2025

Keywords:
Pediatric prescription
Pharmaceutical aspects
Non-Sterile Drugs

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ABSTRACT

Background: Drug compounding is the process of combining, mixing, or changing ingredients in the manufacture of drugs to meet patient needs. The risk of pharmaceutical incompatibility can affect the stability and efficacy of the compounded preparation. **Objectives:** This study aims to determine the pharmaceutical feasibility of non-sterile prescriptions in pediatric outpatients by evaluating dosage forms, concentrations, stability, and potential drug incompatibilities. **Materials and Method:** This study used a cross-sectional design with a purposive sampling technique and retrospective data collection. The sample in this study was 58 sheets of concoction recipes for children in Pulveres form. **Results:** The results showed that all prescription dosage forms were powder, and the strength of the drug was fully stated on the prescription. Based on the results of the study, several prescriptions had the potential for instability, including those containing Ambroxol (1.72%), Cetirizine (3.44%), Codeine (1.72%), Dexamethasone (1.72%), Methylprednisolone (3.44%), Isoniazid (1.72%), Metronidazole (5.17%), Nifedipine (1.72%), Omeprazole (1.72%), Paracetamol (5.17%), Propylthiouracil (3.44%), Ranitidine (3.44%), Rifampicin (1.72%), Salbutamol (10.34%), Triprolidine HCl + Pseudoephedrine HCl (3.44%), Vitamin B complex (1.72%), and Vitamin C (3.44%). Additionally, one prescription contained drugs with potential immiscibility, namely N-acetylcysteine and Erythromycin**.** The drugs Erythromycin, Salbutamol, and N-acetylcysteine were identified as having the potential for incompatibility. **Conclusion:** Vitamin C and Vitamin B complex most frequently exhibited hygroscopic instability and photolytic degradation, therefore it is not recommended to be mixed.

How to cite (APA 6th Style):
Mirawati, M., Kamri, A. M., Ningsih, Y. S. (2025). Pharmaceutical Compatibility of Non-Sterile Mixing Recipes in Pediatric Patients in Covid-19 Pandemic. *Jurnal Farmasi Galenika: Galenika Journal of Pharmacy (e-Journal), 11*(2), 136-147. doi:10.22487/j24428744.2025.v11.i2.16568

INTRODUCTION

Pediatric patients are treated using multiple routes of administration—ranging from oral preparations (pulveres, capsules, syrups) and inhalation to parenteral dosage forms. Children are particularly vulnerable to illness and often require hospital-based care because their immune systems and organ functions are not yet fully developed. Moreover, ongoing growth, frequent interaction with the environment, and play activities—where hygiene cannot always be guaranteed—further increase their susceptibility to disease (Tatterton, 2017).

The hospital is a health service institution for the community. The hospital has pharmaceutical services that support quality health services. The Aeramo Regional General Hospital is the only hospital in Nagekeo Regency. The Aeramo Regional General Hospital is a type C hospital. Compared to the Puskesmas, people prefer to seek treatment directly at the hospital, both from children to the elderly. One of the polyclinics at the Aeramo Regional General Hospital is the Children's Polyclinic. A concoction prescription is a prescription prescribed to outpatient pediatric patients. Considering that pediatric patients prefer to go to the hospital, errors in handling prescriptions may occur, such as errors in Pharmaceutical Aspects which include dosage forms, dosage strengths, drug stability and incompatibility which can interfere with drug efficacy (Yackey & Stanley, 2019).

A prescription is a written request from a physician to a pharmacist to prepare or compound a medication in a specified dosage form for the patient (Sartain et al., 2020). Compounding drugs based on a prescription is a process of combining, mixing or changing an ingredient in the manufacture of drugs that are tailored to individual or patient needs. Concoction drugs are still being prescribed by doctors when providing health services to pediatric patients. The most widely prescribed form of concoction is in solid dosage forms, namely pulveres. Concoction drugs are usually given to pediatric patients because pediatric patients find it difficult to swallow drugs (Haapanen et al., 2022; Landwehr et al., 2019).

However, a concoction recipe consists of many components, resulting in the final product of the concoction not being known with certainty for its complex content, which can lead to problems which include issues of dose uniformity, chemical and physical instability and the possibility of microbial contamination which can affect the efficacy and safety of the drug (Docherty et al., 2017). Therefore, systematic oversight is needed to maintain the quality of pulveres preparations.

Problems related to pharmaceutical appropriateness—covering dosage forms, dosage strengths, drug stability, and incompatibilities—are not uncommon in pediatric prescriptions. Instability in a pharmaceutical preparation may be detected through changes in physical and chemical properties and in appearance. The extent of chemical change is determined by the rate of decomposition over time or

by the degree of degradation; from a chemical standpoint, stability can be assessed by whether there is a decline in active drug levels during storage (Bertsche et al., 2018). Incompatibility is a drug event that is not mixed physically or chemically and results in a loss of potency, increased toxicity or other side effects. This is evidenced by the existence of several studies that have been done before. Based on this study, the problem of drug incompatibility in pediatric outpatient prescriptions in a hospital in Bogor Regency was 3.4% (Rochjana et al., 2019).

From the research that has been done before, this research was carried out to evaluate the pharmaceutical suitability of non-sterile compounded prescriptions for pediatric outpatients at Aeramo Mbay Nagekeo Hospital, East Nusa Tenggara (NTT), Indonesia. This research was carried out based on prescribing problems in non-sterile concoction prescriptions in pediatric patients that often occur which have been proven by previous studies in terms of pharmaceutical aspects. Accordingly, this study focuses on prescriptions issued at Aeramo Mbay Nagekeo Hospital, NTT Province.

MATERIAL AND METHODS

Materials

All prescriptions for pediatric patients were collected at the Aeramo Mbay Nagekeo Hospital in NTT Province for the period May 2020-October 2020. Then a non-sterile prescription was selected for pediatric patients according to the inclusion and exclusion criteria. The data that had been sampled based on inclusion and exclusion criteria is then reviewed based on the literature. The data obtained was tabulated using a statistical application with data analysis methods Descriptive statistics Frequencies according to the observed prescription pharmaceutical aspects. The data obtained was then analyzed using the analytical method Descriptive statistics Frequencies which describes the suitability or not related to pharmaceutical aspects.

Methods

The research conducted was research by design *cross sectional* with retrospective data collection. The sampling technique used in this research is technique *Purposive sampling*, namely a sampling technique based on certain considerations such as population characteristics or previously known characteristics. The inclusion criteria in this study were pediatric prescriptions containing concoctions, pulveres dosage forms, for pediatric patients who received ≥ 1 type of drug, and pediatric concoctions in outpatient installations. The exclusion criteria as a limitation in this study were the doctor's writings which could not be read clearly and concoction recipes that came from outside the Aeramo Mbay Nagekeo Hospital.

RESULTS AND DISCUSSION

This research analyzes non-sterile compounded prescriptions for pediatric patients in terms of pharmaceutical aspects—specifically dosage forms, dosage strengths, drug stability, and incompatibility—based on literature review. Prescriptions for non-sterile pediatric compounds from the Outpatient Pharmacy Department of Aeramo Hospital were collected and assessed according to pharmaceutical criteria obtained from literature.

In Indonesia, compounded prescriptions are often given to pediatric patients because their organ systems and physiological functions are not yet fully developed, making it difficult for them to swallow solid dosage forms. Compounding serves as a practical solution to the limited availability of child-appropriate drug formulations. The total number of prescriptions analyzed was 216, as shown in Table 1.

Table 1. Profile of Prescribing Prescriptions for Children Based on Prescription Sheets at the Outpatient Installation at the Aeramo Mbay Nagekeo Regional General Hospital

No	Period	Number of Recipe Sheets
1	May-20	15
2	Jun-20	34
3	Jul-20	38
4	Aug-20	40
5	Sep-20	39
6	Oct-20	50

In Table 1 it can be seen that in this study for the period May 2020 - October 2020 the population of prescriptions for children at the Outpatient Installation of the Aeramo Regional General Hospital was 216 prescriptions, with the highest number of prescriptions for children in October 2020 with the number of prescription sheets 50 recipe sheets. From the total population of 216 prescriptions, samples were selected using purposive sampling.

In this study, the number of non-sterile recipe samples obtained was 58 recipe sheets. The most non-sterile prescription sheets for pediatric patients were found in September 2020 with 18 prescription sheets and a percentage of 31.03%. Based on descriptive statistical analysis (frequency method), 26 prescriptions (44.8%) contained more than one drug, while 32 prescriptions (55.2%) contained only one drug. Thus, the total of 100% indicates that all samples were valid for analysis.

On the paediatrics prescription sheet, the patient's identity profile that is listed is only gender and body weight, while the age of the patient is not listed. Inclusion of gender in prescriptions is very important

because it makes it easier to recognize male or female patients. We can be seen that the number of male patients who received prescriptions was 26 prescriptions with a percentage of 44.82% and female patients were 32 prescriptions with a percentage of 55.17%. predominate is with the female patients.

Body weight is included to ensure dosage accuracy, as pediatric doses must often be adjusted according to weight (Rauf et al., 2020). The identity profile of patients who use prescription drug concoctions based on body weight intervals is made based on the distribution of children's weight. The identity profile of patients using prescription drug concoctions based on body weight intervals can be seen in Table 2.

Table 2. Profile of Pediatric Patients Prescribing Non-sterile Concoctions Based on Body Weight for the Period May - October 2020

No	Body Weight Intervals (Kg)	Number of Recipe Sheets	Percentage
1	3-5	11	18,96 %
2	5-7	5	8,62 %
3	7-9	25	43,10%
4	10-12	6	10,34%
5	12-14	1	1,72 %
6	14-16	6	10,34%
7	16-18	0	0
8	18-20	2	3,44 %
9	20-22	1	1,72 %
10	22-24	0	0
11	24-26	0	0
12	26-28	1	1,72 %
13	28-30	1	1,72 %

In table 2 it can be seen that pediatric patients who get a lot of concoction prescriptions are pediatric patients with body weight in the 7-9 kg interval with a total of 25 prescriptions with a percentage of 43.10%.

Compounded prescriptions were issued based on each patient’s diagnosis. Each prescription concoction given has various classes of drug therapy with different types of drugs. There are 10 drug therapy classes in the pediatric outpatient prescription sheet, namely Chemotherapy (antibiotics and antivirals), Respiratory System (mucolytics, antihistamines, bronchodilators and Antitussives), Cardiovascular (Diuretics and Antihypertensives), Vitamins, Endocrine (Antithyroid and corticosteroids), Tract digestion (antacids), NSAIDs (analgesic–antipyretic), SSP (anticovulsants, antipsychotics,

antidepressants) anti-tuberculosis and gallstone dissolving drugs. The most frequently prescribed category was chemotherapeutic drugs (antibiotics), totaling 10 prescriptions (17.24%).

It is necessary to know the type of drug in order to make it easier for researchers to analyze data to determine the pharmaceutical aspects of prescriptions for pediatric patient concoctions. Types of drugs prescribed in pediatric patient prescriptions. The results of data analysis using the method Descriptive statistics Frequencies showed that there were 31 types of drugs obtained in this study, with the types of drugs that were often prescribed were N. Acetylcysteine (21.6%) and Salbutamol (16.2%). N. Acetylcysteine is a drug in the mucolytic therapy class used to thin phlegm in the respiratory tract, while salbutamol is a β2-agonist bronchodilator used to treat asthma. The reason many children suffer from diseases of the respiratory tract is due to unstable weather and an unhealthy environment and lifestyle. On the other hand, many Nagekeo residents live in mountainous areas where the mountainous areas have cold temperatures. Children who cannot withstand these temperatures will easily get sick, especially in their respiratory tract, resulting in many pediatric patients with complaints in their respiratory area (Izadpanah et al., 2018; Tatterton, 2017).

Prescriptions may contain one drug or more drugs. To assess potential incompatibility, it is necessary to identify which drugs were combined in the outpatient installation of Aeramo Hospital. The table above shows that the number of different non-sterile children's prescription combinations is 18 drug combinations in recipes containing two to three drugs in them, with drug combinations that are often prescribed repeatedly, there are 8 prescription sheets with a percentage of 30.67% with the type of combination in it is N. acetylcysteine + salbutamol. After determining the prescribing profile on the research data, then a study of pharmaceutical suitability was carried out.

Based on the Regulation of the Minister of Health of the Republic of Indonesia No. 72 of 2016 concerning pharmaceutical services in hospitals, pharmaceutical aspects include dosage forms, dosage strengths, drug stability and incompatibility. In this study, all compounded preparations were pulveres (powders). All ingredients were originally in tablet form, which were crushed into powders**.** Although the exact strength of each preparation was not specified on prescriptions, the doctors stated the dose of each drug, allowing pharmacists to determine the appropriate strength. In this study, drug instability may occur in prescription concoctions containing one or more drugs (Shera et al., 2017).

In the literature search conducted in this study, stability and compatibility data were obtained regarding the drugs contained in the prescription for pediatric patient concoctions at the Aeramo Regional General Hospital Outpatient Installation where this data is the initial data which forms the basis for analyzing the potential for possible instability and incompatibility (Ravn-Nielsen et al., 2018; Unni & Joseph, 2019). Based on the literature search it is known that there are some drugs that are hygroscopic.

Hygroscopic is the ability of a material to attract and absorb water molecules from the atmospheric air in the surrounding environment at room temperature.

The stability of pharmaceutical products is influenced by environmental factors (temperature, humidity, light) and by product-related factors (chemical and physical properties, dosage form, and composition) (Malik et al., 2017). As we know that in the manufacture of drugs, the pharmaceutical industry has considered all stages of making a drug, starting from the initial formulation of the drug to the packaging stage so that the active substance made in the dosage form remains in a stable state. With the presence of compounding, the active substance of the drug which is hygroscopic can affect the stability of the drug itself. A preparation that has been prepared in such a way that its stability is maintained has the potential for changes in stability to occur because compounding involves the process of crushing, mixing and repackaging, during which the active drug substance is exposed to air, light and humidity. Table 3 shows the non-sterile pediatric prescriptions with potential instability due to hygroscopicity.

Table 3. Prescription Profile of Non-Sterile Pediatric Concoction Prescriptions Based on Different Combinations of Prescription Drug Concoctions

No	Drug Combination Type	Number of Recipes	Drug Combination Percentage
1	N. Acetylcysteine + Salbutamol + Metylprednisolon	1	3.84%
2	Phenobarbital + Sprinolakton + Furosemid	1	3.84%
3	N. Acetylcysteine + Salbutamol	8	30.76%
4	N. Acetylcysteine + Salbutamol + Cetrizine	1	3.84%
5	Cefixime + Paracetamol	1	3.84%
6	Vit. C + (Triprolidine HCl and Pseudoephedrine HCl)	1	3.84%
7	N. Acetylcysteine + Vit. C	1	3.84%
8	Vit. B Complex + B1 + B6 + B12	1	3.84%
9	N. Acetylcysteine + Ursodeoxycholic Acid	2	7.69%
10	N. Acetylcysteine + Salbutamol + Eritromicin	1	3.84%
11	Furosemid + Lisinopril + Sprinolakton	1	3.84%
12	N. Acetylcysteine + Triprolidine HCl and Pseudoephedrine HCl	1	3.84%
13	Rimpafisin + Isoniazid + Pyrazinamide	1	3.84%
14	Paracetamol (PCT) + Amitriptilin + Codein	1	3.84%
15	Paracetamol (PCT) + Dexamethason	1	3.84%
16	Cetrizine + Salbutamol	1	3.84%
17	Ambroxol + Salbutamol	1	3.84%
18	Amoxicillin + Cetrizine + Dexamethasone	1	3.84%

The hygroscopic drugs identified were Vitamin C, Vitamin B complex (containing thiamine/B1), Ranitidine hydrochloride, Triprolidine HCl + Pseudoephedrine HCl, and Erythromycin (Sung et al.,

2019). Vitamin C has hygroscopic properties and is not resistant to moisture and Ranitidine HCl is a hygroscopic compound that absorbs moisture from the environment Tremenza which contains Triprolidine HCl and Pseudoephedrine HCl, although stored in tightly closed containers can still experience a decrease in stability (Razani et al., 2019). Triprolidine HCl and Pseudoephedrine HCl are hygroscopic. According to Kurniawan's research, tremenza is hygroscopic (the ability of a substance to absorb water molecules from the environment so that it becomes moist) and deliquescent (the ability of a substance to absorb moisture from the atmosphere so that the substance becomes liquid) will absorb water from the air, so that when mixed with other medicines the powder will get wet, this medicine should be stored in a tightly closed container so that it can slow down the wetting of the powder (Rochjana et al., 2019). Drugs affected by moisture can promote microbial growth, impair aesthetics and destroy active ingredients. The potential percentage for instability in this study was for the drugs Vitamin C 3.44%, Vitamin B1 1.72%, Tremenza 3.44% and Ranitidine HCl 3.44%.

In the results of the literature search, stability was found for light-sensitive drugs such as Methylprednisolone, Nifedipine, and Metronidazole because the stability of these drugs is affected by the presence of light (photolysis). Metronidazole drugs turn dark when exposed to light, Haloperidol is sensitive to light and Rifamipicin is unstable to light, heat, air and humidity.

Table 4 shows that there are drugs that undergo photolysis and do not experience photolysis. The drug undergoes photolysis, meaning that the drug is affected by the presence of light, while it does not undergo photolysis (non-photolysis), meaning it is not affected by light. Drugs that undergo photolysis will experience changes in color, odor, texture, shape or appearance. To deal with drug ingredients that are unstable to sunlight or UV light, during the manufacturing and storage process they must be kept away from sunlight and must not be packaged in ordinary plastic clips because this can damage the drug (Cui et al., 2021; Nanni et al., 2020).

Table 4. Non-sterile prescriptions for pediatric patients who are potentially unstable due to hygroscopicity May-October 2020

No	Medicine Name	Number of Prescriptions Containing the Drug
1	Ascorbic acid (Vit. C)	2
2	Triprolidine HCl and Pseudoephedrine HCl	2
3	Erythromycin	2
4	Ranitidine Hydrochloride	2
5	Vit. B Complex (Thiamine)	1
	Instability presentation	15,51 %

These data indicate that the drugs that undergo photolysis are Ambroxol, Amitriptylin, Cetirizine, Codein, Haloperidol, Isoniazid, Methylprednisolone, Metronidazole, Nifedipine, Omeprazole, Paracetamol, Propylturacil, Ranitidin, Rifampicin, Salbutamol, Triprolidine HCl + Pseudoephedrine HCl, Vitamin B complex from B 6 (Pyridoxine) and vitamin C stability is affected by the presence of light which causes photodegradation of the drug. Vitamin B Complex drugs that contain the active substance Vitamin B6 are photosensitive which if exposed to light results in the loss of the effectiveness of vitamin B6. In addition, the drug Nifedipine when exposed to daylight and artificial light with a certain wavelength, it easily turns into a nitrosophenylpyridine derivative.

The potential for instability that is affected by hydrolysis due to temperature, namely Paracetamol and Amoxicillin drugs where paracetamol drugs must be stored at temperatures less than 45°C, preferably between 15-30°C.^{O}C and amoxicillin should be stored at 20^{O}C or lower. The Aeramo Regional General Hospital Pharmacy itself has good room temperature control, namely by keeping the room temperature at 25^{O}C, with conditions like this where the room temperature is maintained, it is possible that there is no potential for temperature instability in concoction drug preparations. The percentage of photolytic instability in this study were Ambroxol (1.72%), Cetirizine (3.44%), Codeine (1.72%), Dexametasone (1.72%), Methylprednisolone (3.44%), Isoniazid (1.72%), Metronidazole (5.17%), Nifedipine (1.72%), Omeprazole (1.72%), Paracetamol (5.17%), Propylturacil (3.44%), Ranitidine (3 .44%), Rifampicin (1.72%), Salbutamol (10.34%), Tiprolidin HCl+Pseudoephedrine HCl (3.44%), Vitamin B complex (1.72%), and Vitamin C (3.44 %).

In the powder compounding process, the dosage form is usually changed by forming other preparations (tablets are changed into powder form, into solution form, suspension form and others). Such treatment can change the stability of a drug. Where the stability of pharmaceutical products can be affected by the environment such as light, temperature and humidity. In addition to drug stability that can change, drug incompatibility may occur. Incompatibility is a mixture of drugs both physically and chemically and will result in loss of therapeutic effect and may increase toxicity or other side effects. Incompatibility occurred in the prescription of a mixture of 3.84% which mixed N. Acetylcysteine, salbutamol, and Erythromycin.

Potential incompatibility of drugs N. acetylcysteine+ Salbutamol+Erythromycin causes loss of therapeutic effect and increases drug toxicity. Acetylcysteine is incompatible with several metals, including iron and copper, rubber, and oxygen and oxidizing agents. Several antimicrobials including amphotericin B, ampicillin sodium, erythromycin lactobionate, and some tetracyclines are physically incompatible with, or may be inactivated on admixture with acetylcysteine. This can raise the potential for prescription incompatibility (Kraft et al., 2021).

Vitamin C is incompatible with alkalis, heavy metal ions, oxidizing agents, methenamine, phenylephrine hydrochloride, pyrilamine maleate, salicylamide, sodium nitrite, and theobromine salicylate**.** However, no such combinations were found in the analyzed prescriptions. As for Ambroxol, Amoxicillin, Cetirizine, Dexamethasone, Methylprednisolone, Paracetamol, Nifedipine, Isoniazid, Furosemide, Cefixime, Spironolactone, Lisinopril, (Tiprolidin HCl+Pseudoefedrin HCl), Ursodeoxycholic Acid, Acyclovir, Ranitidin, Prazinamide, Phenobarital, Haloperidol, Phenytoin, Omeprazole and Salbutamol showed no incompatibility. Therefore, 96.15% of the compounded prescriptions (25 sheets) showed no incompatibility, while 60.34% contained photolabile drugs (such as Salbutamol, Paracetamol, Isoniazid, Metronidazole, Methylprednisolone, Cetirizine, Triprolidine HCl, Pseudoephedrine HCl, Ranitidine, and Propylthiouracil), indicating potential instability due to photolysis.

CONCLUSION

In accordance with the stability assessment, there is a potential for instability due to the hygroscopic and photolysis of the drug in prescriptions. Drugs with hygroscopic potential include Vitamin B complex, Vitamin C, Triprolidine HCl + Pseudoephedrine HCl, Ranitidine and Erythromycin. Mixing Vitamin B complex and Vitamin C in pediatric powder formulations is not recommended due to instability risks**.**

ACKNOWLEDGEMENT

Thanks to Aeramo Mbay Hospital East and Indonesian Muslim University so that this research can occurred.

CONFLICT OF INTEREST

The authors declare no conflict of interest

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