

[Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Article Processing Charge Confirmation

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Sel 06/12/2022 17.46

Kepada: Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Cc: Dina Christin Ayuning Putri <dinachristin@usd.ac.id>; Dita Maria Virginia <virginia@usd.ac.id>; Michael Raharja Gani <mr_gani@usd.ac.id>; Dika Octa <dikaocta@usd.ac.id>; Pharmaceutics Editorial Office <pharmaceutics@mdpi.com>

Dear Dr. Yuliani,

Thank you very much for submitting your manuscript to Pharmaceutics:

Journal name: Pharmaceutics

Manuscript ID: pharmaceutics-2071201

Type of manuscript: Review

Title: Stability and Compatibility Approach for Quality Assessment of Pharmaceutical Compounding for Pediatric Patients

Authors: Sri Hartati Yuliani *, Dina Christin Ayuning Putri, Dita Maria Virginia, Michael Raharja Gani, Florentinus Dika Octa Riswanto

Received: 17 November 2022

E-mails: srihartatiyuliani@usd.ac.id, dinachristin@usd.ac.id, virginia@usd.ac.id, mr_gani@usd.ac.id, dikaocta@usd.ac.id

Submitted to section: Physical Pharmacy and Formulation,

https://www.mdpi.com/journal/pharmaceutics/sections/Physical_Pharmacy_Formulation

Pharmacy Compounding of Personalized Preparation for Specific Patients:

Challenges and Advantages

https://www.mdpi.com/journal/pharmaceutics/special_issues/0LMCZPN945

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Re: [Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Major Revisions

Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Sel 20/12/2022 21.23

Kepada: marta.spasic@mdpi.com <marta.spasic@mdpi.com>

Cc: Dina Christin Ayuning Putri <dinachristin@usd.ac.id>; Dita Maria Virginia <virginia@usd.ac.id>; Michael Raharja Gani <mr_gani@usd.ac.id>; Dika Octa <dikaocta@usd.ac.id>; Pharmaceutics Editorial Office <pharmaceutics@mdpi.com>

Dear Marta,

Thank you very much for your email. Unfortunately, we are out of office due to the Christmas and new year holiday. Is it still possible for us to submit our revised version after 15 January 2023? We are looking forward for your response.

Regards,
Dr. Sri Hartati Yuliani

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From: marta.spasic@mdpi.com <marta.spasic@mdpi.com> on behalf of Pharmaceutics Editorial Office <pharmaceutics@mdpi.com>

Sent: Tuesday, December 20, 2022 9:02:00 PM

To: Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Cc: Dina Christin Ayuning Putri <dinachristin@usd.ac.id>; Dita Maria Virginia <virginia@usd.ac.id>; Michael Raharja Gani <mr_gani@usd.ac.id>; Dika Octa <dikaocta@usd.ac.id>; Pharmaceutics Editorial Office <pharmaceutics@mdpi.com>

Subject: [Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Major Revisions

Dear Dr. Yuliani,

Thank you again for your manuscript submission:

Manuscript ID: pharmaceutics-2071201

Type of manuscript: Review

Title: Stability and Compatibility Approach for Quality Assessment of Pharmaceutical Compounding for Pediatric Patients

Authors: Sri Hartati Yuliani *, Dina Christin Ayuning Putri, Dita Maria Virginia, Michael Raharja Gani, Florentinus Dika Octa Riswanto

Received: 17 November 2022

E-mails: srihartatiyuliani@usd.ac.id, dinachristin@usd.ac.id, virginia@usd.ac.id, mr_gani@usd.ac.id, dikaocta@usd.ac.id

Submitted to section: Physical Pharmacy and Formulation,

[https://www.mdpi.com/journal/pharmaceutics/sections/Physical Pharmacy Formulation](https://www.mdpi.com/journal/pharmaceutics/sections/Physical_Pharmacy_Formulation)

Pharmacy Compounding of Personalized Preparation for Specific Patients:

Challenges and Advantages

https://www.mdpi.com/journal/pharmaceutics/special_issues/OLMCZPN945

Your manuscript has now been reviewed by experts in the field. Please find your manuscript with the referee reports at this link:

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Please revise the manuscript according to the referees' comments and upload the revised file within 10 days.

Please use the version of your manuscript found at the above link for your revisions.

(I) Please check that all references are relevant to the contents of the manuscript.

(II) Any revisions to the manuscript should be marked up using the "Track Changes" function if you are using MS Word/LaTeX, such that any changes can be easily viewed by the editors and reviewers.

(III) Please provide a cover letter to explain, point by point, the details of the revisions to the manuscript and your responses to the referees' comments.

(IV) If you found it impossible to address certain comments in the review reports, please include an explanation in your appeal.

(V) The revised version will be sent to the editors and reviewers.

If one of the referees has suggested that your manuscript should undergo extensive English revisions, please address this issue during revision. We propose that you use one of the editing services listed at <https://www.mdpi.com/authors/english> or have your manuscript checked by a native English-speaking colleague.

Do not hesitate to contact us if you have any questions regarding the revision of your manuscript. We look forward to hearing from you soon.

Kind regards,
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Assistant Editor, MDPI Belgrade
E-Mail: marta.spasic@mdpi.com

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[Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Response to Academic Editor Comments Required

Marta Spasic <marta.spasic@mdpi.com>

Kam 24/11/2022 19.16

Kepada: Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Cc: Dina Christin Ayuning Putri <dinachristin@usd.ac.id>; Dita Maria Virginia <virginia@usd.ac.id>; Michael Raharja Gani <mr_gani@usd.ac.id>; Dika Octa <dikaocta@usd.ac.id>

 1 lampiran (45 KB)

pharmaceutics-1940862 - Academic Editor Comments.pdf;

Dear authors,

I hope this email finds you well. Thank you for resubmitting your manuscript to Pharmaceutics.

I am contacting you regarding some issues that have to be resolved before we continue processing the manuscript. According to our journal policy, when resubmitting the manuscript the point-to-point response to both reviewers and Academic Editor have to be provided. Since the Academic Editor who provided the final decision for the previously submitted manuscript has made some comments about the issues that should be addressed, please provide us with a response. I am sending the comments you received with final decision in the attachment for your convenience.

Additionally, I would like to confirm with you that you agree with the "Open Review" for this manuscript, since it differs from the option you had chosen for previous submission.

Please forward the responses at your earliest convenience so we could continue processing the manuscript. If you have any questions, do not hesitate to contact me.

Kind regards,

Ms. Marta Spasic
Assistant Editor, MDPI Belgrade
E-Mail: marta.spasic@mdpi.com

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Re: [Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Response to Academic Editor Comments Required

Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Jum 25/11/2022 22.58

Kepada: Marta Spasic <marta.spasic@mdpi.com>

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 1 lampiran (14 KB)

Response to Academic Editor Decision.docx;

Dear Marta,

Thank you for your notification regarding our submission. Herewith, we would like to send our response to the Academic Editor.

We also confirm that we choose the "Close review" similar to our previous submission.

We hope this version of the manuscript can be considered in the next stage of editorial process.

Thank you very much.

Regards,

Dr. Sri Hartati Yuliani

From: Marta Spasic <marta.spasic@mdpi.com>

Sent: Thursday, November 24, 2022 7:16 PM

To: Sri Hartati Yuliani <srihartatiyuliani@usd.ac.id>

Cc: Dina Christin Ayuning Putri <dinachristin@usd.ac.id>; Dita Maria Virginia <virginia@usd.ac.id>; Michael Raharja Gani <mr_gani@usd.ac.id>; Dika Octa <dikaocta@usd.ac.id>

Subject: [Pharmaceutics] Manuscript ID: pharmaceutics-2071201 - Response to Academic Editor Comments Required

Dear authors,

I hope this email finds you well. Thank you for resubmitting your manuscript to Pharmaceutics.

I am contacting you regarding some issues that have to be resolved before we continue processing the manuscript. According to our journal policy, when resubmitting the manuscript the point-to-point response to both reviewers and Academic Editor have to be provided. Since the Academic Editor who provided the final decision for the previously submitted manuscript has made some comments about the issues that should be addressed, please provide us with a response. I am sending the comments you received with final decision in the attachment for your convenience.

Additionally, I would like to confirm with you that you agree with the "Open Review" for this manuscript, since it differs from the option you

had chosen for previous submission.

Please forward the responses at your earliest convenience so we could continue processing the manuscript. If you have any questions, do not hesitate to contact me.

Kind regards,

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to “Prevalence, risk, and challenges of extemporaneous preparation for pediatric patients in developing nations: A review”. We checked the structure and make a better connection between title, aim, methodology, and discussion. We focused our discussion on pediatric patients. Hence, we also highlight our main aim to provide patient-oriented compounding practice in developing nations. The amendments as well as the major corrections are highlighted in the manuscript with the green colored fonts.

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Notes File

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Is the work a significant contribution to the field? ★ ★ ★ ★ ★

Is the work well organized and comprehensively described? ★ ★ ★ ★ ★

Is the work scientifically sound and not misleading? ★ ★ ★ ★ ★

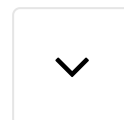
Are there appropriate and adequate references to related and previous work? ★ ★ ★ ★ ★

Is the English used correct and readable? ★ ★ ★ ★ ★

Comments and Suggestions for Authors

It appears that authors haven't made any significant correction to previous version of the manuscript. Paper is still poorly structured in regard to its title and defined aim. Also, methodology is unacceptable.

The biggest part of this paper which should be a review of available literature concerning stability and compatibility in compounding for pediatric patients is written as a handbook. It seems that authors wish to show all relevant aspects for compounding of pediatric drugs whit the specific concern for the compounding process in developing countries. And we can read a paper with lot of facts substantiated by references. Yet, a topic – given by the title and the defined aim, and that is, a review on the quality assessment based on stability and compatibility of extemporaneous pediatric preparations is missing. The question of stability and compatibility is elaborated at one and a half page of the manuscript. And moreover that part is written more like



theoretical background regarding stability, without adequate experimental references related to the studies conducted in order to investigate stability.

This review is not in accordance to its title and defined aim. This paper looks like a review of challenges related to compounding pharmaceutical practice for pediatric patients in developing countries. And in this case authors should make necessary changes regarding the title and the aim of this paper. Still, even with a different title and aim, methodology in this paper is unsatisfactory.

Submission Date	17 November 2022
Date of this review	07 Dec 2022 13:49:54

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Prevalence, risk, and challenges of extemporaneous preparation for pediatric patients in developing nations: A review

General comments:

This is now very meaningful paper with research which answers the aim.

Response to Reviewer 1

We thank the reviewer for the comments. We also appreciate the reviewer for the positive effort to improve our manuscript's quality.

Author's Report Notes (/user/review/displayFile/33628479/r6yU9aXN?file=author-coverletter&report=26524340)

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Is the work a significant contribution to the field? ★ ★ ★ ★ ★

Is the work well organized and comprehensively described? ★ ★ ★ ★ ★

Is the work scientifically sound and not misleading? ★ ★ ★ ★ ★

Are there appropriate and adequate references to related and previous work? ★ ★ ★ ★ ★

Is the English used correct and readable? ★ ★ ★ ★ ★

Comments and Suggestions for Authors
 This is now very meaningful paper with research which answers the aim.

Submission Date
 17 November 2022

Date of this review
 20 Jan 2023 13:45:34



Prevalence, risk, and challenges of extemporaneous preparation for pediatric patients in developing nations: A review

General comments:

Thanks much for taking into consideration the comments and revising the manuscript. The revised version is much better. I would suggest discussing the paediatric focussed challenges related to stability and incompatibility related to quality assessment. Giving few pediatric specific examples might help.

Also, please note that the excipients are of concern and several factors needs to be taken into consideration such as route, dose, amount, diseases sverity, funactionality. Can you provide any specific examples where excipients have been used for extemp preparation and led to serious adverse effects?

Response to Reviewer 2

Thank you for the reviewers' valuable comments. We have revised the manuscript and made several improvements. The revised parts were highlighted in the manuscript with the green colored fonts.

The manuscript was revised as follows:

“Several literature review have summarized the safety and toxicity of pharmaceutical excipients for pediatric patients. The health profesional should increase their awareness related to the risk of adverse event of exipients. Some exipients, such as arginin, aspartam, paraben, polyethyleneglycol, polysorbate, sorbitol, ethanol, etc., have reported giving adverse reaction. Parabens were the highest reported excipients and linked with several cases of adverse reactions in the pediatric population. Further, parabens were also associated with hypersensitivity reaction in pediatric, especially for neonatus. Other study was reported the risk of medication with sorbitol as exipient which has a potential negative effect such as diarrhea. Hence, it is important to consider the medication of pediatric and critically disease patients. The daily admissible intake of sorbitol according to European excipient review is limited to 5 mg/kg in children 0-2 years old, and 140 mg/kg in those older than 2 years.” (Line 157-168)

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Is the work a significant contribution to the field?	★	★	★	★	★
Is the work well organized and comprehensively described?	★	★	★	★	★
Is the work scientifically sound and not misleading?	★	★	★	★	★
Are there appropriate and adequate references to related and previous work?	★	★	★	★	★
Is the English used correct and readable?	★	★	★	★	★

Comments and Suggestions for Authors

Thanks much for taking into consideration the comments and revising the manuscript. The revised version is much better. I would suggest discussing the paediatric focussed challenges related to stability and incompatibility related to quality assessment. Giving few pediatric specific examples might help.

Also, please note that the excipients are of concern and several factors needs to be taken into consideration such as route, dose, amount, diseases sverity, funactionality. Can you provide any specific examples where excipients have been used for extemp preparation and led to serious adverse effects?

Submission Date 17 November 2022

Date of this review 23 Jan 2023 15:55:24



made the significant revision which we hope to meet the approval. The amendments as well as the major corrections are highlighted in the manuscript and this rebuttal file with the green colored fonts.

=====

There are many other reasons why extempers are prepared for paedes and leads to adverse events such as medication preparation errors, dose accuracy, availability, affordability for LMICs, lack of appropriate formulation, different dosage forms, different age groups.

Response:

We have revised the manuscript as follow:

“The use of licensed drugs for pediatric patients has the potential to be dangerous, because excipients are not suitable for children, even if administered in small amounts. Since extemporaneous compounding was described as a branch of pharmacy practice to produce appropriate pharmaceutical preparations when there are no commercially available, licensed, and age-specific dosage forms, the problems related to stability, pharmacokinetic profile, and drug effect potentially occurred.”

We also added the statement as follow:

“Further, pharmacists require to control stability, compatibility, as well as provide formulation information to ensure patients were supplied with safe, high-quality, and effective preparations.”

Why was the keyword paediatrics not included?

Response:

We have added “pediatrics” as one of the keywords.

Spell the abbreviation when used for 1st time.

Response:

We have revised and added the abbreviation “International Monetary Fund (IMF)” in the manuscript.

It is bit offbeat. The article does not flow well. Some text are abruptly included. For example. In this case, the prevalence in different countries is discussed and then drugs are listed. Is this country specific or common to all countries listed above?

Response:



We have revised the manuscript. We have removed the abrupt content and focused on the topics.

Thailand is excluded from table. Is there any particular reason?

Response:

We have added a study from Thailand.

It is highlighted several places in the article that it is important to ensure quality, however, the reasons for doing so is missing. Also examples are missing to highlight the impact. Did you come across any references where assessing the quality has resulted in positive outcome while not doing so as resulted in negative outcome?

Response:

We have revised the manuscript. The importance to ensure quality of extemporaneous preparation was to provide patient-oriented medication. This statement was added in abstract section to strengthen the aim of the paper. We did not come across any references.

As mentioned earlier, it abruptly moves to different routes. It might be helpful to consolidate common areas/themes for discussion.

Response:

We have carefully evaluated the usage of gentamicin and hydrocortisone for pediatrics patient, especially for the treatment of scabies.

Is this pediatric product???

Response:

Thank you for the comments. We have removed inappropriate citations to the topics.

The section states general issues .. nothing specific to paediatric population.

Response:

We have revised the manuscript and focused on pediatric population.

I believe inappropriate reference is stated and discussed here. There are many references where excipients such as suspending agents are used for extemporaneous and has led to side effects. Such references should be discussed. The scope of the article is not to discuss issues of excipients of excipients in general but to



to discuss issues of excipients related to compounding.
Clinicians/pharmacists struggle to find appropriate safety information to make informed decision on selection of excipients for compounding such issues should be discussed in this paper

Response:

Thank you for the suggestion. We have removed inappropriate references and kept the supported references. The safety information related to the excipient of concern were discussed in the section of the challenges of compounding practices.

I would restrain from using the word 'harmful' as it depends on the several factors, age group, route, etc. which are not discussed in this paper. Inclusion of the excipients in the product does not necessarily mean they are harmful, you need to assess the dose, amount, route of administration, severity of diseases, dosage form, age group. etc. You can call them excipients of concern but not declare them harmful.

Response:

We have revised the manuscript and changed the phrase 'harmful' into 'excipients of concern'.

Do you intend to focus the paper on developing countries?? then it would be good to reflect that in title. Also, please refer to terminology of developing countries. Today, the preferred terminology is a **developing nation**, an underdeveloped country, or a low- and middle-income country (LMIC).

Response:

We have changed the terminology of developing countries into developing nations.

This table is not needed or needs to be replaced with information specific to compounding effects of excipients? This is not new and has been included several times in the literature so appropriate references summary the adverse effects of excipients can be included instead of table.

Response:

We kept providing the table since Table 2 presented a summary or list regarding excipients of concern for children.

are these for paediatric population?

Response:



According to the cited article, it was reported that ambroxol hydrochloride and salbutamol sulfate were prescribed for pediatrics in our previous study.

again what is relevance to paediatric?

Response:

According to the cited article, it was reported that acetylsalicylic acid was prescribed for pediatrics in Brazil as a developing nation. However, the usage of acetylsalicylic acid should be evaluated further according to the toxicity report of acetylsalicylic acid for pediatrics medication.

no mention of paediatric?

Response:

In the section of "Lack of regulatory guidance" we have mentioned pediatrics limitedly. However, it is common knowledge that regulations covered several aspects of medication in different ages. We also mentioned a case of children's death related to compounding failure.

Overall, the article is not well articulated. Several elements are missing. the quality assessment aspects is very vaguely discussed. It more highlights the issues with compounded preparation but again very abruptly. This is an important area which needs attention for betterment of children

Response:

We have revised the structure of manuscript. We also change the title of the manuscript in order improve the relevance between title and the whole manuscript. We also strengthen the manuscript by focusing the discussion on pediatric patients.

Author's Notes File [Report Notes \(/user/review/displayFile/33839704/febnET6U?file=author-coverletter&report=25247277\)](/user/review/displayFile/33839704/febnET6U?file=author-coverletter&report=25247277)

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Is the work a significant contribution to the field?



Is the work well organized and comprehensively described?	★ ★ ★ ★ ★
Is the work scientifically sound and not misleading?	★ ★ ★ ★ ★
Are there appropriate and adequate references to related and previous work?	★ ★ ★ ★ ★
Is the English used correct and readable?	★ ★ ★ ★ ★

Comments and Suggestions for Authors

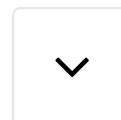
This article provides a review on the quality assessment of pharmaceutical compounding products. It covers few important aspects, however, they are very vaguely discussed and very limited references are included. The introduction is very weak and does not clearly explain the rationale of the paper. I would help to give some examples on how quality has impaired the health of pediatric populations or impact of quality on health of pediatric population. The article does not match the title. Title mentions paediatric, however introduction does not focus on paediatrics and neither the aims and objectives. Does that article aim to highlight the need of quality assessment of extemp preparations or does it aim to include the different methods of quality assessments. It is very vague and does not clearly focus on one or other aspects. The aim suggests that the authors provides the review on several aspects but then it needs to summarise a short section on what aspects it covers as there are many other aspects that are not even listed in the paper. Hence the research work on this topic seems to be very limited for a review.

The attached pdf provides further detailed comments. I hope you find them helpful for the revision of the article. All the best!

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Submission Date 17 November 2022

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We sent a revision request for the following manuscript on 20 December 2022.

Manuscript ID: pharmaceutics-2071201

Type of manuscript: Review

Title: Stability and Compatibility Approach for Quality Assessment of Pharmaceutical Compounding for Pediatric Patients

Authors: Sri Hartati Yuliani *, Dina Christin Ayuning Putri, Dita Maria Virginia, Michael Raharja Gani, Florentinus Dika Octa Riswanto

Received: 17 November 2022

E-mails: srihartatiyuliani@usd.ac.id, dinachristin@usd.ac.id, virginia@usd.ac.id, mr_gani@usd.ac.id, dikaocta@usd.ac.id

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Received: 17 November 2022

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Manuscript ID: pharmaceutics-2071201

Type of manuscript: Review

Title: Prevalence, risk, and challenges of extemporaneous preparation for pediatric patients in developing nations: A review

Authors: Sri Hartati Yuliani *, Dina Christin Ayuning Putri, Dita Maria Virginia, Michael Raharja Gani, Florentinus Dika Octa Riswanto

Received: 17 November 2022

E-mails: srihartatiyuliani@usd.ac.id, dinachristin@usd.ac.id, virginia@usd.ac.id, mr_gani@usd.ac.id, dikaocta@usd.ac.id

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Type of manuscript: Review

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Authors: Sri Hartati Yuliani *, Dina Christin Ayuning Putri, Dita Maria

Virginia, Michael Raharja Gani, Florentinus Dika Octa Riswanto

Received: 17 November 2022

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