Author’s response to reviews

Title: Superior silybin bioavailability of silybin-phosphatidylcholine complex in oily-medium soft-gel capsules versus conventional silymarin tablets in healthy volunteers

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Author’s response to reviews:

November 29, 2018

Stephen Madamba
Editor of BMC Pharmacology and Toxicology

Dear Stephen Madamba

I am pleased to resubmit for publication the revised version of Manuscript PHAT-D-18-00016R2 entitled “Superior silybin bioavailability of silybin–phosphatidylcholine complex in oily-medium soft-gel capsules versus conventional silymarin tablets in healthy volunteers”. We appreciate the efforts of the editor and reviewers in this manuscript. We are very grateful for your comments. We have revised the paper based on your valuable comments using tracked changes option. As below, on behalf of the co-authors, I would like to answer point-by-point to the comments of the Reviewers. I hope you find the manuscript fine.

Sincerely

Prof. Nahum Méndez-Sánchez, MD, MSc, PhD, FAASLD, FACP, AGAF

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Reviewer’s comments Response/Correction

1. In your funding section, please also state the role of the funding body in the design of the study; collection, analysis, and interpretation of data; and in writing the manuscript. Note that this is a standard requirement, with no implications of impropriety on your part.

   In the funding section we explained that the study was partially sponsored by ITALMEX-SA.

   ITALMEX SA as a funding body provided assistance to the researches in methodology for the study and provided grants for any material requested for the study by the researchers.

   The above is specified in line 249 of the “funding” section.

2. In addition, please revise the funding statement so that it addresses all forms of support provided by Italmex Pharma. Support may include but is not limited to: professional laboratory services, provision of grants, provision of materials, etc.

   ITALMEX SA provided professional laboratory services and provision of material for the tests. It also supports the researchers with the methodology of the study.

   The above is specified in line 249 of the “funding” section.

3. In the Ethics and consent to participate section please clarify whether consent to participate was written or verbal. If the consent was verbal please include reasoning for this and state if an IRB approved this method of obtaining consent. The participants granted their written consent to participate in the study. The document that they signed was approved by the Ethics & Investigation Committee of Nucleo Clínico de Bioequivalencia, S.A. de C.V. (NABIO) and the Mexican Health Authority (COFEPRIS). You can find this new information in line 237, in “Ethics approval and consent to participate” section.

4. Please include the date of trial registration with the Trial registration number in the abstract. If the date of registration is after the date that the first participant was recruited, please also state ‘retrospectively registered’. Please also include the name of the registry.

   The study was registered on November 11, 2016 since the first patients was recruited. This information is stated on line 52 in the “abstract” section.
5. Please upload your figures as separate figure files and remove them from the main manuscript file. When uploading the figure files, please make sure they contain the image graphic only and not the titles or captions. Please place the titles and captions in the main manuscript after the References.

The figures are now in another file. The main manuscript does not include images or tables.

6. We note that the current submission contains some textual overlap with other previously published works, in particular:


This overlap mainly exists in the Methods section. We understand that it may be impractical to rewrite or omit the methodology described in your paper to avoid overlap with previous publications, therefore we ask that you reference/acknowledge the original article where this methodology was first published.

The references mentioned are now cited in the main text. You can find it in lines 117-118 of “methods” section

7. Please remove the Author Declarations forms from the file inventory, as they are no longer needed at this stage of the editorial process.

N/A

8. Please change the “Materials and methods” headings in the Abstract and the main text to “Methods”.

We changed to Methods, both in the abstract and in the main text.

9. At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different
colors. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

The final manuscript does not contain any figures or tables. All the correction we made it and the rest of the text are in the same format, without highlights or comments.