

Current Pharmaceutical Analysis

Manuscript Evaluation Form

Editor-in-Chief: Anastasios Economou, Department of Chemistry, Laboratory of Analytical Chemistry, University of Athens, Athens, Greece

PAPER TITLE	The Impact of Analytical Quality by Design (AQbD) in the Method Development of Liquid Chromatography for Quality Control of Pharmaceuticals: A Review
AUTHOR(S) NAME	Mohsin M. Shaha, Amol S. Jagdale, Shaikh Ismail

Sec. A: REFEREE'S ASSESSMENT

(cross as appropriate)

Criterion	Excellent	Good	Fair	Poor
Originality of the topic	x			
Technical Quality		x		
Importance in its Field	x			
Style & Overall Representation		x		
Readily Understandable	x			
Suitability for the Journal	x			
Adequate Illustrations or Drawings	x			
English language		x		
Description	Yes	No	Comments/ Suggestions	
Does the title represent manuscript's contents?	x			
Is the Abstract accurate and concise?	x			
Are the approach/ methods properly described?	x			
Are the conclusions and interpretations sound?	x			
Are the references properly cited?	x			
Is this a new/ original/ contribution?	x			
Is it within the scope of the journal?	x			
Overall the Paper is Rated:	(Excellent ----- Poor) 10 9 8 7 6 5 4 3 2 1			

Sec. B: REFEREE'S RECOMMENDATIONS

OTHER SPECIFIC CRITICISMS

Accept with minor changes

Imperfect style

Accept with major changes

Too long

Reject in current form, but may be resubmitted

References incorrectly presented

Reject, with no resubmission

Typographical and Grammatical errors

PAPER TYPE: Research article

Review article

Letter article

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Confidential Comments to the Editor (not for Transmission to Authors):

This review is within the scope and suitable for the journal after some revision.

Comments for the Authors (continue on another sheet, if necessary):

Review of the article entitled

The Impact of Analytical Quality by Design (AQbD) in the Method Development of Liquid Chromatography for Quality Control of Pharmaceuticals: A Review,

by Mohsin M. Shaha, Amol S. Jagdale, Shaikh Ismail

This review article provides a comprehensive understanding on different steps of analytical quality by design (AQbD), along with their concern ICH guidelines. Analytical quality by design involves the following steps: analytical target profile (ATP) critical quality attribute (CQA), method design, critical process parameters (CPP), risk assessment: (failure mode effects analysis–FMEA, Ishikawa diagrams-fishbone diagrams), design of experiment (DOE), identification of significant and insignificant factors using design expert software, design space (DS), method operable design region (MODR), control strategy and process analytical technology (PAT). The application of QbD principles to the analytical method development is focused on the concept of building quality into the method during development, instead of testing methods for quality after development. This review is within the scope and suitable for the journal after some revision.

The English language, grammar and spelling have to be improved.

State the complete term and the abbreviation at the first place where it appears in the manuscript, in the rest of the text use either the abbreviation or full term.

Add the list of abbreviations at the end of the manuscript.

Use the abbreviations e.g. and i.e. instead of eg. and i.e

One space should be added or deleted at the adequate places in the manuscript, between some words and numbers.

Arrange figures by numbers in the order in which they are mentioned in the text.

Numbers of some figures should be corrected.

On page 7, in the paragraph Risk assessment, the correct number and labeling of figure is

Figure 2, instead of figure no-3

On page 8, in the paragraph Ishikawa diagram (Fishbone diagram), the correct number and labeling of figure is Figure 3, instead of figure no-02

On page 10, the last sentence of the second paragraph should be: Diagrams for MODR and ADS are shown in Figures 4 and 5.

The correct numbers of Figures on page 18 are Figure 4 and Figure 5, instead of 5 and 6.

Similarly, in the attachment at the end of the manuscript, the correct number of figure on page 16 is Figure 3,

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and on page 17, Figure 2. These two pages should be replaced.

Place all the Figures with their legends and all the Tables with the captions at the place where they are mentioned in the text of the manuscript.

Label the Figures with Figure 1, Figure 2, Figure 3, 4 and 5, as well as Tables with Table 1, Table 2 and 3.

Put the points after the legends of Figures 1, 2, 3 and 4.

Caption of Table 2 should be bold

The quality or the overall presentation of some Figures and Tables can be improved.

For example, resolution of Figure 3 (currently 2) can be improved

In Figure 2 (currently 3), visibility of letters in the subject Risk acceptance can be improved

In Table 1, use the quotes at the adequate places

In Table 2, the third column should be centered

On page 3, separate subheading ICH Q10 guideline from the paragraph

On page 7, state the name of the paragraph Risk analysis, instead of repeated

Risk analysis Risk analysis

On page 8, state Design of Experiment, instead of Design Of Experiment

Complete the references, format the entire manuscript and references according to the style of the journal

In reference 1, add numbers of pages

In reference 2, add number of volume, issue and pages

In references 3 and 4, add numbers of volumes, issues and pages

In references 5 and 6, add numbers of issues

In reference 7, add the year

Some more references can be added, if it is possible and available.

FIELD OF EXPERTISE OF REFEREE: Materials and chemical technologies, nanotechnologies, biomedical engineering, chemistry, medicinal and pharmaceutical chemistry

Name & Affiliation of referee: Tamara Jovanovic, Department of Biomedical Engineering, Faculty of Mechanical Engineering, University of Belgrade, Kraljice Marije 16, 11120 Belgrade, Serbia

Dr Tamara Jovanovic / February 3, 2019

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