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	Risk Assessment, Screening and Control of Elemental Impurities in Pharmaceutical Drug Products: A Review
AUTHOR(S) NAME	Rajesh Kumar Chawla, Subhranshu Panda, K. Umasankar, Siva Prasad Panda and D. Damayanthi

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 -8---------- Poor)** 10 9 **8** 7 6 5 4 3 2 1

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Accept with minor changes	x	Imperfect style	x
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PAPER TYPE: **Research article** ☐ **Review article** ☐ **Letter article** ☐

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

This review article represents an important study within the scope of the journal. It is suitable for publication after some revision that I suggest and send in the comments for the authors.

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

Review of the article entitled
Risk Assessment, Screening and Control of Elemental Impurities in
Pharmaceutical Drug Products: A Review, by Rajesh Kumar Chawla, Subhranshu Panda, K. Umasankar, Siva Prasad Panda and D. Damayanthi

This article describes and reviews the steps involved in risk assessment of elemental impurities in drug products, based on the permitted daily exposure limits for the twenty four (24) elements that are considered as potential elemental impurities. Screening and estimation of elemental impurities in drug substances, excipients and drug products by Inductively Coupled Plasma Mass Spectrometry or Inductively Coupled Plasma Optical Emission Spectrometry and their controls involved are also reviewed, as referred in the general chapters <232> & <233> of the United States Pharmacopoeia, Q3D guideline for Elemental Impurities as per International Conference on Harmonization and Q3D Elemental Impurities: guidance for Industry as per U. S., Food and Drug Administration US-FDA.

The article represents an important study within the scope of the journal. It is suitable for publication after some revision that I send in the comments for the authors.

The English language has to be improved.
For example, in the Introduction, replace hence should be brought down to the safety levels, if any, instead of should be bring down
Replace EIs testing is now becoming mandatory, instead of is now become mandatory
On page 8, replace Generally, sample preparation can be done by direct dissolving in aqueous or organic solvent, etc.
In Key words, Screening and control can be added after Risk assessment.
On page 3, at the end of the first sentence of the section Risk assessment of elemental impurities product, add (Table 1) and place Table 1 with the table caption after this sentence or at the end of the first paragraph.
On page 4, replace (μg/day), instead of (the μg/day)
On page 6, the correct unit of measure for permitted daily exposure, PDE in the Equation 1 is (μg/day), instead of (μg/g)
Put the label (1) next to Equation 1
Move subheading Option 2a, as well as subheading Option 3 to the next page
Cite references 35-37 within the first paragraph of the section Controls, instead of in the title of this section
Check that the entire manuscript is formatted according to the style of the journal.

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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 / January 19, 2019
SIGNATURE OF REFEREE / DATE