

Review Form 1.7

Journal Name:	Biotechnology Journal International
Manuscript Number:	Original Manuscript_BJI_117924
Title of the Manuscript:	Development and validation of chromatographic methods for the quantification of impending genotoxic impurities in Dapson drug substances
Type of the Article	

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<https://www.journalbj.com/index.php/BJI/editorial-policy>)

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>Compulsory REVISION comments</p> <p>1. Is the manuscript important for scientific community? (Please write few sentences on this manuscript)</p> <p>2. Is the title of the article suitable? (If not please suggest an alternative title)</p> <p>3. Is the abstract of the article comprehensive?</p> <p>4. Are subsections and structure of the manuscript appropriate?</p> <p>5. Do you think the manuscript is scientifically correct?</p> <p>6. Are the references sufficient and recent? If you have suggestion of additional references, please mention in the review form.</p> <p>(Apart from above mentioned 6 points, reviewers are free to provide additional suggestions/comments)</p>	<p>1. Currently, the Genotoxic and Nitrosamine impurities is the major topic in the pharmaceutical industry. Hence, the research work carried out by the author is precious in current pharmaceutical industry.</p> <p>2. Yes</p> <p>3. The abstract is comprehensive.</p> <p>4. Yes</p> <p>5. The research is scientifically sound.</p> <p>6. ICH 7</p>	
<p>Minor REVISION comments</p> <p>1. Is language/English quality of the article suitable for scholarly communications?</p>	<p>1. The author should include the method development experiments in experimental part.</p> <p>2. Suggested to author, ensure the entire article for grammatical and spelling mistakes.</p> <p>3. Suggested to author, simply the linearity curves in single figure and ensure the data.</p> <p>4. The author must include Acknowledgement and Conflict of interest in the manuscript.</p> <p>5. As mentioned in the abstract batch analysis has been performed but not included batch details and results.</p> <p>6. Sample chromatograms should be available in manuscript.</p> <p>7. Suggested to author, include EMA guideline and many articles published on GTI and Nitrosamines related topic.</p> <p>8. Suggested to author, re-check the reference style as per journal guidelines.</p>	
<p>Optional/General comments</p>	<p>The quality of paper can be improved including method development experiments and addressing the observations in reported methods.</p>	

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PART 2:

	Reviewer's comment	Author's comment <i>(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)</i>
Are there ethical issues in this manuscript?	<i>(If yes, Kindly please write down the ethical issues here in details)</i>	

Reviewer Details:

Name:	Ediga Sasikirangoud
Department, University & Country	India