Review Form 3

Journal Name:	**Journal of Pharmaceutical Research International**
Manuscript Number:	**Ms_JPRI_126718**
Title of the Manuscript:	**A Comprehensive Guide to Applicative Requirements for Analytical Method Validation Across Various Regulatory Guidance: ICH, USP, ChP and ANVISA**
Type of the Article	**Review Article**

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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.
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PART 1: Review Comments

Compulsory REVISION comments	**Reviewer's comment**	**Author's Feedback** *(Please correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)*
Please write a few sentences regarding the importance of this manuscript for the scientific community. Why do you like (or dislike) this manuscript? A minimum of 3-4 sentences may be required for this part.	This manuscript is significant for pharmaceutical and regulatory professionals, providing an essential comparison of method validation guidelines (ICH, USP, ChP, ANVISA). It aids in understanding regulatory differences, promoting efficient and harmonized practices across markets.	
Is the title of the article suitable? (If not please suggest an alternative title)	The title is informative but could be clearer. Consider: "Comparative Analysis of Analytical Method Validation Requirements Across ICH, USP, ChP, and ANVISA."	
Is the abstract of the article comprehensive? Do you suggest the addition (or deletion) of some points in this section? Please write your suggestions here.	The abstract should briefly highlight key differences between guidelines and summarize practical impacts for industry compliance. Adding one or two sentences on these points would strengthen its clarity.	
Are subsections and structure of the manuscript appropriate?	The manuscript's structure is organized well, with clear subsections for each regulatory body's guidelines, making it accessible and easy to navigate. However, a clearer differentiation or explicit comparison between regulatory frameworks in each section would enhance readability, as would the addition of tables summarizing each guideline's requirements for quick reference. These improvements would support both scientific rigor and user-friendliness.	
Please write a few sentences regarding the scientific correctness of this manuscript. Why do you think that this manuscript is scientifically robust and technically sound? A minimum of 3-4 sentences may be required for this part.	The manuscript is scientifically robust as it captures specific validation parameters (e.g., accuracy, precision, specificity) and evaluates them against each regulatory standard, which is essential for technical soundness in pharmaceutical quality control. The detailed exposition on forced degradation, robustness, and linearity requirements across guidelines is particularly useful. This comparative approach enhances understanding of regulatory nuances, making the manuscript a technically valuable reference.	
Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form. **-**	The references included are relevant and support the content effectively. However, a few recent publications on regulatory harmonization and analytical validation methodologies could be added to strengthen the literature review, especially given the evolving landscape of regulatory standards.	
Minor REVISION comments **Is the language/English quality of the article suitable for scholarly communications?**		
Optional/General comments	A diagram or Graphical Abstract would enhance the Article more.	

PART 2:

	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)*
Are there ethical issues in this manuscript?	*(If yes, Kindly please write down the ethical issues here in details)*	

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