|  |
| --- |
|  |
| Book Name: | [**Pharmaceutical Science: New Insights and Developments**](https://www.bookpi.org/bookstore/product/pharmaceutical-science-new-insights-and-developments-vol-1/) |
| Manuscript Number: | **Ms\_BPR\_5962** |
| Title of the Manuscript:  | **Development and Validation of a Stability-Indicating RP-HPLC Method for Simultaneous Estimation of Duloxetine and Methylcobalamin in Bulk and Tablet Dosage Form** |
| Type of the Article | **Book Chapter** |

|  |
| --- |
| PART 1: Comments |
|  | Reviewer’s comment**Artificial Intelligence (AI) generated or assisted review comments are strictly prohibited during peer review.** | 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. A minimum of 3-4 sentences may be required for this part.** | This publication advances the field of pharmaceutical analysis by offering a reverse-phase HPLC method for the simultaneous measurement of Duloxetine and Methylcobalamin, two therapeutically important drugs used in neuropathic diseases. The development and validation of such a system is critical for providing consistent quality control in combination dosage formulations, which are increasingly being used in clinical settings. If enhanced and supported by complete stability data, this method could provide a practical and reproducible solution to regular pharmaceutical analysis, benefiting both industry and regulatory compliance. The work has the potential to fill a methodological gap, assuming its uniqueness and robustness are clearly proved through further validation elements. |  |
| **Is the title of the article suitable?****(If not please suggest an alternative title)** | The term "stability-indicating" is either premature or unjustified in the absence of forced degradation experiments. Better correct it as"Development and Validation of an RP-HPLC Method for Simultaneous Estimation of Duloxetine and Methylcobalamin in Bulk and Tablet Dosage Forms" |  |
| 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. | Stability-indicating assertion is not supported:The abstract states that this is a "stability-indicating" approach, however no forced degradation experiments are stated.Suggestion: Either give a brief description of degradation studies, or remove "stability-indicating" if they are not present.Abstract is excessively long and repeated in various areas: Can be somewhat condensed for better readability. |  |
| **Is the manuscript scientifically, correct? Please write here.**  | The manuscript's underlying methodology and analytical approach are scientifically correct.However, the claim of a "stability-indicating" method is not validated due to a lack of degradation investigations. Furthermore, certain validation factors (e.g., LOD/LOQ, increased robustness testing) are missing and should be addressed to ensure that the study is fully consistent with regulatory standards and scientifically comprehensive. |  |
| **Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form.****-** | Some sources, such as textbook citations ([1]-[5], [7]-[9]), are more than 15-20 years old. Recent literature is lacking. • The majority of analytical method articles are from 2010-2015, with no references beyond 2015. • The references are adequate but not up-to-date. To improve the manuscript, include 2-3 recent (post-2018) peer-reviewed articles and update regulatory references. A brief explanation comparing your method to the most similar existing methods (especially reference [20]) is strongly encouraged to demonstrate innovation. |  |
| Is the language/English quality of the article suitable for scholarly communications? | We recommend a professional language edit to enhance clarity and an academic, scientific tone. |  |
| Optional/General comments | **Methodology & Experimental Design**1. For stability-indicating claims without forced degradation data, please provide degradation studies and chromatograms proving the method's capacity to differentiate active components from degradation products.
2. System suitability. Parameters are incomplete.Please include resolution and retention factor (k′) values to meet pharmacopeial standards.Although the introduction suggests scant past study on this drug combination, there are various contemporary approaches available (including those indicated in your own reference list).
3. Please research the literature and compare your approach to existing ones for sensitivity, simplicity, run time, and matrix application.LOD/LOQ Not Reported.The ICH rules mandate reporting of Limit of Detection (LOD) and Limit of Quantification (LOQ).
4. Please specify the values and the method used (e.g., signal-to-noise or standard deviation of slope).
5. Validation of precision is lacking. Statistical depth: While %RSD values are presented, no confidence intervals or ANOVA were done to ensure reproducibility.Consider conducting statistical analyses to validate intra-day and inter-day variations.
6. Methylcobalamin's accuracy exceeds acceptable limitsThe recovery values for MCB at 50% and 150% levels (105.65% and 106.98%) exceed tolerable limits.
7. Review your recovery methods to determine if matrix effects or sample handling are contributing to the divergence.
8. “Less Time-Consuming” Claim is Questionable

A 10-minute run time is relatively long by modern RP-HPLC or UPLC standards.1. Please justify this claim or consider optimizing your method to reduce analysis time.

Robustness Validation Is Superficial,The robustness section tests only limited parameters (flow rate and mobile phase composition).1. Consider including additional robustness factors such as analyst-to-analyst variability and column-to-column reproducibility.
 |  |

|  |
| --- |
| **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)* |  |

**Reviewer details:**

**Mallamma T, India**