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| Journal Name: | [**Asian Journal of Research and Reports in Urology**](https://journalajrru.com/index.php/AJRRU) |
| Manuscript Number: | **Ms\_AJRRU\_131490** |
| Title of the Manuscript: | **An in-vitro dissolution profile and impurity analysis comparing commercially available dutasteride tamsulosin fixed drug combinations** |
| Type of the Article | **Original Research Article** |

**General guidelines for the Peer Review process:**

**Artificial Intelligence (AI) generated or assisted review comments are strictly prohibited during peer review.**

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: 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.** | **the dissolution and impurity profiles of FDC formulations for BPH, providing insights into their quality, efficacy, and safety, which can improve patient outcomes and guide regulatory standards.** | Thanks for the comment. |
| **Is the title of the article suitable?**  **(If not please suggest an alternative title)** | **Yes it's ok** | Thanks for the response. |
| 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. | **Its comprehensive but check the format as per journal guide line.** | Thanks for the response. |
| Is the manuscript scientifically, correct? Please write here. | Yes, the study is **scientifically correct** as it follows established methodologies for dissolution and impurity testing, and the results align with regulatory standards, ensuring reliability and validity. | Thanks. |
| **Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form.** | Reference needs improvement and refer some recent paper and well indexed paper. | Thanks for the response. But the references applied are required to support the sentences. |
| Is the language/English quality of the article suitable for scholarly communications? | yes | Thankyou. |
| Optional/General comments | 1.The introduction is a good overview of BPH and treatment but is somewhat unfocused. Consider making the section on the pathophysiology of BPH shorter and the rationale for studying the dissolution and impurity profiles of these specific formulations longer.  2.Dissolution Testing: The procedure for dissolution testing is well-written, but the rationale for the specific conditions (e.g., pH, rpm) is not as clear. Why were these conditions chosen, and how do they reflect the in vivo condition?  Impurity Testing: The procedure for impurity testing is clear, but the authors need to discuss the significance of the impurities being tested. Why were these specific impurities chosen, and what are their possible effects on drug efficacy and safety?  3.Dissolution Profiles: The results show that Dutas T+ had the highest dissolution rate, but the authors need to discuss whether this difference is clinically significant. For example, does a higher dissolution rate necessarily mean in better patient outcomes?  Impurity Profiles: The absence of detectable impurities is a good finding, but the authors need to discuss the possible implications of even trace amounts of impurities that were not detectable by the methods used. | 1. Rationale has been added, while the pathophysiology has been shortened as follows*:* *For fixed drug combinations like dutasteride and tamsulosin, the dissolution profile can reveal differences in the release rates of each component, which can impact their absorption and efficacy. By comparing the dissolution profiles of different formulations, we can identify which products provide optimal release and absorption, leading to better clinical outcomes for patients. This analysis also helps in maintaining batch-to-batch consistency and overall product quality.* 2. The dissolution media was chosen as per the physiological pH of stomach and intestines.   For impurity testing, the significance of the test impurities is mentioned as follows:  *The laboratory examination of dutasteride during its development revealed a few impurity peaks in HPLC that ranged from 0.05 to 0.1%. By LCMS method, the identified impurities were Desmethyldutasteride, and Dihydrodutasteride (citation attached in revised manuscript draft).*   1. The significant difference in dissolution of Dutas T+ was seen as compared to brand C. A statement related to clinical implication added.   The implications of trace amount impurities are mentioned in the manuscript under the limitations as follows:  *Other limitation might include minor undetectable impurities by the methods used. Further in vivo study using other methods of impurity detection can be explored.* |

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| **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)* | NA |

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| **Reviewer Details:** | |
| Name: |  |
| Department, University & Country |  |