Review Form 1.6

Journal Name:	**Journal of Pharmaceutical Research International**
Manuscript Number:	**Ms_JPRI_80262**
Title of the Manuscript:	**A Stability Indicating RP-HPLC Method Validation for Simultaneous estimation of Metformin HCl, Dapagliflozin and Saxagliptin in pharmaceutical dosage form.**
Type of the Article	**Original Research 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:

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(https://www.journaljpri.com/index.php/JPRI/editorial-policy) 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)*
Compulsory REVISION comments	1. **Aim of the research work was to develop and validate novel, rapid, sensitive, specific, robust stability indicating analytical method for simultaneous estimation of : Metformin HCl, Dapagliflozin and Saxagliptin in pharmaceutical dosage form as fixed dose formulation. The obligatory question is what is the practical usefulness of this validation method in the clinic? Or is it only a method to establish if the suggested dose is adequate? Is this only applicable to the laboratory? How long does this test take? how much blood does the patient require? These questions are not answered, it just says that it** it can be utilize for routine or unknown sample analysis of assay of Metformin HCl, Dapagliflozin and Saxagliptin in pharmaceutical dosage form developed by various Pharmaceutical Industry 2. A new, rapid, sensitive, specific and robust RP-HPLC method indicating stability for the fixed dose **formulation** of metformin, dapagliflozin and saxagliptin. New is possible, fast they do not explain why, the sensitivity, specificity and solidity are explained but the stability depends on the drug and the dose is established according to the stability, solubility, pharmacokinetics and dynamics, so the usefulness of the test is only for the laboratory that produces the drug and its recommendation regarding dosage and not for patients **3. This should** be **explained in a better way, The great utility of this test is to establish safety in the doses, and they should guide the work in that direction.** **4. some bibliographic references should be improved in order to locate them**	1. We are thankful for providing valuable suggestions to pur research work. The first thing we would like you clarify here is that the Quality product is prime concern now a days in Pharmaceutical industry. Therefore, We would like to inform reviewer that purpose of proposed research work in the manuscript is to develop and validate the analytical procedure for simultaneous assay of Metformin HCl, Dapagliflozin and Saxagliptin in Pharmaceutical Dosage Form in Quality control or R&D Laboratory or to check the unknown concentration in marketed product which is claimed as furious or adulterated as well as to ensure quality of the Product. Proposed methos is for analysis of synthetic samples only prepared from Pharmaceutical Dosage form such as Tablet. We would also like to inform reviewer that proposed method is not suitable for analysis of plasma samples of patient in clinic. In addition, proposed method was developed and validated for all parameters such as specificity, Linearity, Precision, Accuracy Robustness and solution stability as recommended by ICH and UFDA in "Validation of Analytical Procedure: Methodology Q2B". Based on that it is concluded that proposed method is suitable for routine assay sample analysis of Pharmaceutical Dosage form for Metformin HCl, Dapagliflozin and Saxagliptin. 2. We are thankful for providing valuable comments. We here by confirm that proposed method is for analysis of pharmaceutical dosage form in laboratory only. This method is not suitable for analysis of patient samples in Clinical. The method is not bio-analytical. 3. We here by confirm that proposed method is for analysis of pharmaceutical dosage form in laboratory only. This method is not suitable for analysis of patient samples in Clinical.(Method is not bioanalytical) Hence this method cannot be used to establish safety in the dose in patient.

		4. We are thankful for providing valuable comments. We have checked the manuscript and all relevant applicable references are included in the manuscript.
Minor REVISION comments	5. **improve** graphic	5. Most of the graphics included in manuscript are software generated. However, we have checked manuscript again and ensure correctness in revised manuscript.
Optional/General comments	6. Maybe **they** should reorganize the writing in terms of its items and make a more precise conclusions or discussion.	6. We have checked the manuscript for accuracy and precision of result and discussion in relevance to proposed manuscript. Same is provided in revised manuscript.

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)*	