Review Form 1.6

Journal Name:	**Journal of Pharmaceutical Research International**
Manuscript Number:	**Ms_JPRI_82141**
Title of the Manuscript:	**Development of GC method for analyzing Potential Genotoxic Impurities at low-level determination in Atorvastatin Calcium**
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.
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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)*
Compulsory REVISION comments	Corrections i. Please write in full all abbreviations used. E.g. GC, HPLC, MMS etc. ii. 'Every one of the reagents utilized were HPLC-grade with ≥99% virtue.' Please explain this sentence in a better and simpler form for easy comprehension iii. What do you mean by the word 'virtue'. Please replace with appropriate scientific word iv. Avoid starting a sentence with abbreviation e.g. i. '**AR**-grade methanol……..'. ii. '**MMS**, EMS, IPMS and BB were isolated on AT-5…..'. iii. '**LOQ**s and LODs were characterized as the fixations…….' v. Avoid starting a sentence with figures e.g. '**1µl** infusion volume of 18.75 ppm…….' vi. **Try to make your methods simpler to understand** e.g. '……The restriction of recognition of Impurity A-D were 1.9, 1.5, 1.0 and 0.8, not set in stone at the most minimal fixations at which signal-to-clamor proportion is 3 and 10'. vii. These sentences are most appropriate for the Results and discussion section. **The author is discussing and justifying his results in the Materials and methods section.** Please move them to the Results and discussion section. See below:- **a. 'The technique approval results summed up in Table 1 show that our set up strategy can dependably measure these PGIs in ATC.'** b. **ii. 'The low % RSD esteems by means of pinnacle regions affirm the great accuracy of the created strategy (Table 1)'.** c. **iii. '**The recuperation information introduced in (Table 1) shows the exactness of the strategy. Clear and standard chromatograms are displayed in Figure 1-5. In the changed gas chromatographic states of ±5°C on the underlying broiler temperature and transporter gas stream ±0.5 psi, the maintenance times and pinnacle spaces of Impurities A-D were observed to be same demonstrating the heartiness of the strategy'. d. Arrangement dependability has been set up for a time of 24 h and the Similarity factor of the standard arrangements of Impurities A-D are 0.97, 0.96, 0.96 and 1.03 individually. **e. Test Analysis** f. The approved GC strategy was applied to gauge the previously mentioned PGIs in three clusters of ATC tests. The test convergence of ATC was 20.0 mg/mL, and that of the standard blend containing contaminations A-D was 200 ng/mL. The outcomes are recorded in Table 1. The levels of all PGI contaminations were underneath the characterized satisfactory TTC limits, in this manner demonstrating that all pollutants are very much controlled. **g. Test Analysis** h. The approved GC strategy was applied to gauge the previously mentioned PGIs in	

	three clusters of ATC tests. The test convergence of ATC was 20.0 mg/mL, and that of the standard blend containing contaminations A-D was 200 ng/mL. The outcomes are recorded in Table 1. The levels of all PGI contaminations were underneath the characterized satisfactory TTC limits, in this manner demonstrating that all pollutants are very much controlled. viii. 'This work intended to foster a touchy and dependable GC strategy to evaluate PGIs in Atorvastatin Calcium/ATC. Division of ATC and its four PGIs done on an AT-5 (30 m×0.53 mm×5.0 µm) hairlike section under programming temperature. acetonitrile was utilized as diluent'. **This should go to the introduction section as it will form part of the aim for the experiment.** ix. Because the author had already presented part of his results I the Materials and methods section; he failed to present the results in the Results section and went straight discussing the work. The right thing to do is to present your results and discuss it accordingly e.g '). The constraint of quantitation of Impurity A-D are 6.1, 3.8, 2.5 and 2.0 ppm separately. The constraint of discovery of Impurity A-D are 1.9, 1.5, 1.0 and 0.8, still up in the air at the most reduced focuses at which signal-to-clamor proportion is 3 and 10. The created GC strategy was upgraded dependent on the goals of Impurities A-D and approved according to ICH rules. The strategy well suits for the expected reason'. **x.** The author first arguments that look like result were introduced without making references to the sources of the figures. Are they from Table 1,2 etc or figures 1,2 etc **'Toxnet logical information uncovers that Impurities A-D are distinguished as class-1 according to ICH M7. As far as possible were set up as 18.75 ppm for the four PGIs (Impurities A-D) by thought to be the greatest day by day measurement of Atorvastatin Calcium 80 mg'.** xi. The author cited 11 references in the manuscript. And all the 11 references are contained in the introduction section with known in the **Materials and Methods** section and the **Results and Discussion** sections respectively. xii. The author didn't present his results well and consequently failed to discuss his findings xiii. The abstract section is supposed to summarise the work. Little from the introduction section, material and Methods section Results and Discussion section and Conclusion. Abstract is deficient xiv. The author tend to refer to the work as review when he or they carried out investigation	

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Minor REVISION comments	Yes	
Optional/General comments	The work is novel and should be accepted for publication after revision appropriately carried out	

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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