



SDI Review Form 1.6

Journal Name:	International Research Journal of Pure and Applied Chemistry
Manuscript Number:	Ms_IRJPAC_50076
Title of the Manuscript:	Determination of Amlodipine Besilate and Azilsartan Medoxomil by UHPLC, HPTLC and Spectrophotometric techniques
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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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	<p>) Author stated the methods were validated as per ICH, but the method validation is missing many parameters</p> <ol style="list-style-type: none"> 1) Specificity of method 2) Forced degradation of method 3) Solution stability 4) Mobile phase stability 5) Ruggedness study (on different day, different system and different analyst) 6) Filter study 7) Robust ness (wrt to Flow , temperatue, mobile phase compositions and sample preparation parameters) <p>2) As per ICH guidance all the assay quantification methbods are stability indicating, but the developed HPTLC and Spectrophotometric techneques are not stability indicating.</p> <p>3) Accuracy is proved at 100% concentration only, but as per ICH it should cover minimum at 80% and maximum 120%</p> <p>4) Range of the experiments is also not established.</p> <p>5) The manuscript is missing the development part of these 3 methods</p> <p>Overall the study is not upto the mark and manuscript can be accepted after addressing the</p>	<ol style="list-style-type: none"> 1 Specificity- In Discussion (page 9), It has been stated that it was determined by applying the proposed methods to synthetic prepared mixtures containing different ratio of the two drugs. And both drugs was determined in synthetic tablets without any interference from excipients. 2 Three methods are not stability indicating method so no forced degradation method is present 3 Solution stability was studied and added 4 Ruggedness was done through using mobile phase from different source and was added 5 Robustness was done (through change in mobile phase composition and flow rate) and was added in the manuscript 6 Three methods are not stability indicating method. Two methods (UHPLC& HPTLC) for determination of both drugs in combination and one spectrophotometric method for determination of amlodipine in presence of azilsartan without any interference from azilsartan. 7 Accuracy of three methods ranged from 99.52 to 101.05% and it is within the acceptance range 8- In Discussion (page 8), It has been stated that concentration ranges of 2- 20 µg/ mL and 4-40 µg/ mL by UHPLC method and 0.2 -4.0 µg/ spot and 0.5- 8.0 µg/ spot by HPTLC method for ALD-B and AST-M, respectively. The visible spectrophotometric method was found to be valid over the



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	above comment	concentration range of 10–80 µg/mL ALD-B.
<u>Minor</u> REVISION comments		
<u>Optional/General</u> comments		

PART 2:

	Reviewer's comment	Author's comment <i>(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)</i>
Are there ethical issues in this manuscript?	<i>(If yes, Kindly please write down the ethical issues here in details)</i>	It was not applicable