

Review Form 1.6

Journal Name:	Journal of Pharmaceutical Research International
Manuscript Number:	Ms_JPRI_84421
Title of the Manuscript:	DEVELOPMENT & VALIDATION OF RP-HPLC METHOD FOR QUANTITATIVE ESTIMATION OF DASATINIB AND ITS IMPURITIES IN PHARMACEUTICAL DOSAGE FORM
Type of the Article	Research

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)
<u>Compulsory</u> REVISION comments	<p>This paper study the separation and quantification of Dasatinib and its impurities by HPLC method. The results could be of interest to readers, but revision is required before this could be considered acceptable. The comments listed below need to be addressed.</p> <p>1.HPLC method is used in this paper, but the LC method is written in the conclusion of ABSTRACT, are they consistent?</p> <p>2.The wavelength for measurement was selected as 320 nm from the absorption spectrum, where is the the absorption spectrum data? Does it come from literature or your experimental data?</p> <p>3.The data of stationary phase selection was written in the 3.4. Selection of mobile phase, such as "Poor peak shape and resolution was observed when Zorbax SB C18 (250mm x 4.6mm, 5μ) and gradient mobile phase programmed of Mobile Phase: ", is it more reasonable if the3.3 and 3.4 will be integrated?</p> <p>4.In the figure: 1.5, the such Sample was written, which Sample was "such Sample"? Can you give more clearly information?</p> <p>5. About 13 Chromatographic peaks can be seen in the figure:1.5, why choose these impurity peaks(Impurity-D, Impurity-A, Impurity-F, Impurity-C, Impurity-E) for determination ?Can you give more detail describe about it?</p> <p>6.There are the tailed phenomenon of the dasatinib chromatographic peak in the figure: 1.6, how much the tailing factor is there in the experiment? Does it comply with the regulations? Can you give more discuss in the manuscript?</p> <p>7.Only 3 drug concentrations in the standard curve experiment(Figure: 1.7, Figure: 1.8, Figure: 1.9, Figure: 1.10, Figure: 1.11, Figure: 1.12) is too little and needs to be supplemented more drug concentrations.</p> <p>8.Can you give more experimental details in the Accuracy? How many experiments were repeated for the sample of Imp-A, Imp-C, Imp-D, Imp-E, Imp-F? The deviation data of the results should be supplemented in Table: 1.12.</p>	<p>Both are consistent.</p> <p>Based on literature data</p> <p>Agreed, ok we have corrected in the revised paper.</p> <p>As such sample means (control sample) without spike any known impurities.</p> <p>In control sample monitoring known and unknown impurities in total impurities calculations.</p> <p>Agreed, but tailing factor or asymmetry calculated in related substances only in diluted standard or reference solution (concentration is 0.2%). But figure 1.6 sample concentration is 2000 ppm.</p> <p>Linearity study performed 3 levels (lower level 0.1% to 1.0% higher level). In this linearity study RRF (Relative response factor) also calculated</p> <p>The recovery samples were prepared triplicate preparations for each concentration level. But table 1.12 results mentioned mean % recovery.</p>
<u>Minor</u> REVISION comments		
<u>Optional/General</u> comments		

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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?	<u>(If yes, Kindly please write down the ethical issues here in details)</u>	