



**SDI Review Form 1.6**

**PART 1:**

Journal Name:	<b><u>British Journal of Pharmaceutical Research</u></b>
Manuscript Number:	<b>2013_BJPR_5515</b>
Title of the Manuscript:	<b>Solid state characterization and effect of PEG 20000 and lecithin on particle size reduction and stability of complexed glibenclamide nanocrystals</b>
Type of the Article	<b>Research Paper</b>

**General guideline for Peer Review process is available in this link:**

**(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)**

- This form has total 7 parts. Kindly note that you should use all the parts of this review form.



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**PART 2: Review Comments**

	<b>Reviewer's comment</b>	<b>Author's comment</b> <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>
<b>Compulsory</b> REVISION comments	<p>This paper presents some nice data on solid state characterization of glibenclamide nanocrystals and examines the effects of complexation with lecithin on such properties as size, zeta potential, crystallinity, thermal behaviour and morphology.</p> <p>While the experiments appear to have been rigorously performed in most cases, there are some instances where the experimental approach could be improved or described in more detail; these are given below.</p> <p>Some of the interpretation of the data acquired is dubious and in some cases is simply wrong. The authors need to reconsider and revise the conclusions they present on the basis of the results acquired.</p> <p><b>Abstract</b> Line 11 – it is not clear what is meant by “compatibility” Line 26 – how can particles in the solid state resemble micelles? This is nonsensical.</p> <p><b>Introduction</b> Line 46 – The sentence beginning “although a number of nanoformulations ....” does not make much sense and should be rephrased. Line 56 – the need for polymer degradation only applies to systems containing polymers.</p>	



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	<p>Line 68 – I presume the authors mean “alter the surface properties” rather than “increase the surface properties”?</p> <p>Line 78 – The abbreviation “ADME” should be given in full.</p> <p>Line 81 – Glibenclamide should be written in full as this is the first instance of use of the abbreviation, i.e. Glibenclamide (GLB)...</p> <p><b>Methods</b></p> <p>Line 101 – What concentration of GLB solution was used?</p> <p>Line 101 - How much PEG was added?</p> <p>Line 103 – What was the rate of addition to the aqueous phase?</p> <p>Line 105 – What volume was adjusted to 100 ml?</p> <p>Line 106 – What temperature was used?</p> <p>Details of all equipment used in experiments should be provided – make and model of e.g. centrifuge, oven etc.</p> <p>Line 117 – What was the rate of addition</p> <p>Line 118 – What is the melting point?</p> <p>Line 120 – What is the purpose of the mannitol?</p> <p>Line 124 – Add “prepared in 2.2.2 above” after “homogenous dispersions”.</p> <p>Line 128 – What temperature was the desiccator held at?</p> <p>Line 140 – Were 5 runs performed on the same sample? Were different samples of the same batch not measured? I notice no standard deviations are provided for the average particle size or PDI. This is poor practice.</p> <p>Line 148 – Was this 3 scans of the same sample or 3 different samples of the same batch?</p> <p>The authors should state how many replicate measurements were taken for PXRD, DSC and FTIR.</p>	
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	<p>Line 161 – Were pinholes used in DSC lids? Line 168 – What ratio of KBr to sample was used?</p> <p>Line 178 – If the vials were airtight the effect of RH wasn't really assessed.</p> <p><b>Results and Discussion</b></p> <p>Line 189 – This sentence should be rephrased – the complexed NCs were found to have smaller particle sizes than the equivalent uncomplexed systems.</p> <p>Line 191 – the PDI of F5 was not below 0.5</p> <p>Line 198 – This sentence makes no sense. It should be rephrased. The charge is due to the lecithin coating presumably.</p> <p>Line 200 – Where are the carboxyl groups? This sentence makes no sense.</p> <p>Line 212 – PXRD will not allow you to detect interactions between drug and polymer unless a new chemical entity is formed (e.g. complex, salt etc.)</p> <p>Line 240 – Why does GLB raw material display a double peak on the DSC? The interpretation of the DSC results is simply wrong. PEG is a crystalline, not an amorphous, polymer Why do the authors refer to glass transition temperatures? You will only see a Tg for an amorphous material. You cannot refer to Tgs of crystalline materials.</p> <p>Line 286 – How can solid particles resemble micelles? This makes no sense.</p> <p>Figure 4. The scale on figure 4(C) is not clear – it should be to the same scale as 4(B) and 4(D).</p>	
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	<p>Figure 294 – Was the stability study done on complexed or non-complexed F1? It would have been useful to compare the two systems – (i.e. with and without lecithin). Table 3 shows no standard deviations!</p>	
<p><b><u>Minor</u></b> REVISION comments</p>	<p>In general the English needs to be carefully corrected throughout the manuscript, I would suggest by a native English speaker. The number of instances of corrections that should be made is too numerous to detail here.</p> <p>Line 126: mbar NOT m bar</p> <p>Line 138: I don't understand this sentence.</p>	
<p><b><u>Optional/General</u></b> comments</p>		

**Note: Anonymous Reviewer**