



SDI Review Form 1.6

PART 1:

Journal Name:	<u>British Journal of Pharmaceutical Research</u>
Manuscript Number:	2013_BJPR_3923
Title of the Manuscript:	Formulation And Evaluation Of Carbamazepine 200 Controlled Release Tablets Using Different Methocel Grades
Type of the Article	Research paper

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

	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>
<p>Compulsory REVISION comments</p>	<ol style="list-style-type: none"> 1. Abstract: The purpose of the work is not clearly stated. Based on the obtained results, the conclusion is general and it cannot be concluded what the meaning of performed tests is. 2. The introduction should be supplemented by examples of HPMC formulations with carbamazepine, ie Paragraph 2 of the <i>Preparation of carbamazepine 200 mg CR tablets</i> section should be part of the Introduction. 3. The aim of the study is not clear enough: was it the development of more robust formulations by using different techniques with various types of HPMC, the quality of which will remain in compliance with the specification requirements? What exactly the authors wanted to achieve this way? There was no comment related to Tegretol CR 200 mg tbs which was later referred as the reference product. 4. In the entire paper it is necessary to harmonize names eg. HPMC 100 is sometimes referred to as HPMC 100 and sometimes as HPLC 100 LV; HPMC 2910 is also referred to as HPMC E5 and so on. 5. The titles above certain tables are missing. 6. What does the term <i>geometrically mixed</i> mean? 7. In the manufacturing procedure it is not mentioned when SLS was added. 8. For DC formulation it is stated that <i>it is also (!?!)</i> tested in different buffer media, and the results compared to those obtained in the previous study. Which previous study? What criteria were used for this comparison? Under which conditions the reference product was tested? 9. DSC thermal analysis: The authors did not test all combinations of API and polymer used (eg results for HPMC K4M are missing). 	



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	<p>10. Why the dissolution rate was monitored within 4h (distilled water+1% SLS)? All other tests were carried out during 24 hours, while for adequate analysis of the obtained results it is necessary to perform testing within 24h in water as well.</p> <p>11. Based on the obtained results the influence of solubilizer present in the medium of carbamazepine dissolution rate is evident, so this topic should be commented. It is not clear how f_2 factor was calculated and which profiles were compared?</p> <p>12. What is the purpose of calculating f_2 factors, possibly omitting the BE studies? If that was the goal then the tested formulations must be compared vs the reference product, Tegretol CR 200 mg tbs.</p>	
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<p>1. Minor REVISION comments</p>	<ol style="list-style-type: none"> 1. Colorcon formula should be explained in more details. 2. Generally, the tables should be reorganized. 3. Since the tests included determination of dissolved API as a function of time, the dissolution rate was more correct term than dissolution. 4. Since the pharmacopoeial requirements define the number of samples used for average weight, average hardness and assay, it is not clear to what the comment below some of the Tables "all values are expressed as mean \pmSD (n=3)" refers to. 5. For the dissolution profiles comparison 12 tablets should be tested. 6. The following statement is not correct: <i>According to USP limits tablets prepared by 0,5% and 1% SLS are confirming to USP limits after 3, 6, and 24h and not conform after 12h.</i> F8 does not meet the requirement after 3, nor does F5 after 6 and 12h (both formulations contain 1% SLS). 7. In the Table 5 buffer pH 2.0 was written instead of pH 1.2. 8. Conclusion should briefly state the major findings of the study as written in the Authors Instruction. This part should be completely rephrased. 9. The references are not fully cited in accordance with the Authors Instructions. 	
<p>10. Optional/General comments</p>	<ol style="list-style-type: none"> 1. Only the starting materials used for the preparation of formulations and the reference product should be mentioned. 2. The pharmaceutical synonyms are Hardness and Crushing strength of tablets instead of Hardness and Crushing value. 3. In the pharmaceutical industry purified water is used. 4. What was the point of testing the tablets from the beginning, middle and end of tableting phase? 	

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