



SDI Review Form 1.6

PART 1:

Journal Name:	British Journal of Pharmaceutical Research
Manuscript Number:	2013_BJPR_4104
Title of the Manuscript:	A Study Investigating the Extent of Absorption and Pharmacokinetics of a Newly Developed Paracetamol/Caffeine Formulations Containing Sodium Bicarbonate in Healthy Volunteers

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.



SDI Review Form 1.6

PART 2: 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>This manuscript reports bioequivalence (BE) study between RAPC and Panadol Extra products. The followings are my comments</p> <p>Major comments</p> <ol style="list-style-type: none"> 1. Please recheck the regulation on BE test The C_{max} of paracetamol in fasted state is not bioequivalent. Then, RAPC is not bioequivalent. 2. Change the title. I cannot see any data on "extent of absorption". 3. Add the rationale for semi-fed states. Is RAPC planned to be administered two hours after meal? 4. Add the mechanism of bicarbonate for faster absorption rate of both paracetamol and caffeine. 5. Calculate the rate of absorption (k_a). It is a better parameter than AUC_{0-30min} and AUC_{0-60min}. Figures 1 and 2 clearly show the greater AUC_{0-30min} and AUC_{0-60min} for RAPC. 6. If the terminal phases of acetaminophen and caffeine are clear both all subjects, use AUC_{0-∞}. Otherwise, use AUC_{0-10 h}. 7. Change the followings <ol style="list-style-type: none"> a) Line 20 'clinical bioequivalence' to the 'pharmacokinetic bioequivalence' b) Line 58 'Moller' to the 'Møller' c) Line 82 Delete the over the counter. 	



SDI Review Form 1.6

	<ul style="list-style-type: none">d) Lines 97-100 and 108-115 The contents were mentioned before.e) Line 104 Add reference(s) after (PK) study.f) Line 122 Blood sampling<ul style="list-style-type: none">1) Add 'sample' after blood (line 123).2) Add blood and plasma volume collected3) Add contents of heparin (* units/ml) at lines 124 and 126.4) Line 127; Add the actual blood sampling times.5) Lines 129-131; Add the reference. Add the linear ranges, detection limits, retention times, CVs, etc for both paracetamol and caffeine.g) Line 136 'speed' to the 'rate'h) Line 141 and elsewhere The "trapezoidal method" to 'trapezoidal rule method'.i) Line 146<ul style="list-style-type: none">1) What kinds of regulations (USA or EU) were used?2) Add the α-value.j) Line 148 Add reference(s) after SAS.k) Lines 175-177 Make one sentence. <p>8. The format for quotation of references in the text is different with other Journals.</p> <p>9. Tables 1 and 2 Delete the "comparisons".</p> <p>10. Tables 3A-6 Delete and mention briefly in the text.</p> <p>11. Figures 1 and 2<ul style="list-style-type: none">a) Make 2 figures for fed and semi-fed.b) Add SD.c) Use semi-log paper to see clearly the terminal phase.</p>	
--	---	--



SDI Review Form 1.6

Minor REVISION comments		
Optional/General comments		

Note: Anonymous Reviewer