



SDI Review Form 1.6

PART 1:

Journal Name:	<u>British Journal of Pharmaceutical Research</u>
Manuscript Number:	2013_BJPR_4083
Title of the Manuscript:	Stability of an aspirin in the aspirin+curcumin admixture at different storage conditions
Type of the Article	Short Research Articles

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 (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		We appreciate your comments.
Minor REVISION comments	<p>2.3 HPLC method Mobile pH 3.3 is obtained by mixing 0.1% formic acid in distilled water or it is being adjusted? Please clarify.</p> <p>2.4 standard solutions 1 mg/ml standard aspirin stock dissolved in 75% ethanol is not clearly understood what is the remaining portion of diluents 25 %? Stability of standard solution should be studied and demonstrated, % RSD should be within acceptable levels.</p> <p>2.4 sample analysis A 5µl sample was injected into HPLC system. What was the injection volume of standard solution, Please clarify the injection volume of standard solution.</p>	<p>2.3 HPLC method We corrected it into "The mobile phase consisted of distill water, acetonitrile and formic acid. (v/v/v, 45/55/0.05, pH 3.3)." (line 71)</p> <p>2.4 standard solutions We corrected it into "A 1 mg/mL of stock solution of aspirin was prepared by dissolving in 75%(V/V) ethanol/DW." (lines 83 and 84) And we added that "The results were within limits (%RSD <10)" (line 112)</p> <p>2.4 standard solutions We added that "The injection volume was 5 µL" (line 85)</p>



SDI Review Form 1.6

	<p>3.0 Results and discussion</p> <p>As per ICH please demonstrate and establish Specificity of the chromatographic method. Precision was established at n=5, As per ICH precision should be established minimum 6 determinations at the 100% of the test concentration.</p> <p>Fig 1 (B) Representative chromatograms only shown with DW, please include individual chromatograms of NS solution too.</p> <p>Table 3. : Please clarify the stability study n=7 for 25⁰C, 4⁰C temperature and n=8 for -20⁰C . Actual concentrations of Aspirin is varying from 19.64 % to 31.01 % as compared to the target value of 25%, please explain. “% Concentration remaining” how the values obtained is not clear, please explain the</p>	<p>3.0 Results and discussion</p> <p>According to the ICH (November 1996), precision should be assessed using: (1) A minimum of 9 determinations covering the specified rang for the procedure (e.g., 3 concentrations/3 replicates each); or (2) A minimum of 6 determinations at 100 percent of the test concentration.</p> <p>We used " a minimum of 25 determination covering the specified range for the procedure (e.g., 5 concentrations/5replicates each). Therefore our precision tests meet the ICH guidelines.</p> <p>We added that "Fig. 1. (C) Chromatogram of aspirin(25 µg/mL in NS) and asprin+curcumin admixture (25µg/mL+150µg/mL in NS) after 0, 1st, 3rd and 7th days of storage at 25 °C ." (line 125)</p> <p>We corrected Table3(line 152)</p>
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	calculations. Please include additional column of actual concentration recovered.	
<u>Optional/General</u> comments	Please include sample / standard solution filter type and porosity in	We added that "The filter with pour size of 0.22 μm (Millipore, Milford, MA, USA) was used for filtration of mobile phase and 0.45 μm (PALL, USA) for filtration of standard and sample solution."(line 47)

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