



**SDI Review Form 1.6**

Journal Name:	<a href="#">British Journal of Pharmaceutical Research</a>
Manuscript Number:	Ms_BJPR_18952
Title of the Manuscript:	mAb Higher Order Structure Analysis with Protein Conformational Array ELISA
Type of the Article	Original Research Article

**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.

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**PART 1: 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 study has been carried out based on the suggestion that the HOS status of formulated mAb can be assessed by PCA ELISA directly without any treatment, and the result further emphasized the opinion that PCA technology can be a valuable technology for mAb formulation development.</p> <p>But there are some questions should be cleared before the manuscript be published :</p> <p>1) In this study , both IgG1 and IgG2 mAbs were analyzed for their HOS status mainly under stressed conditions. For example , the effect of exposure to increased temperature was examined for both IgG1 and IgG2 mAbs respectively. The IgG1 sample incubated at 55°C for 10 days was compared to a control sample (Fig. 1A), while an IgG2 sample (IgG2-a) stored at 40°C for 14 days was compared to the corresponding control sample (Fig. 1B). In addition, they also examined the impact of glycation and de-glycosylation,</p>	



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	<p>exposure to pH extremes and light exposure on the mAb HOS.</p> <p>Could the author explain whether the experiment result obtained under such stressed conditions (other than norm conditions )are still of value in the elucidation of the impact of bioprocess and formulation conditions on the HOS of the mAb ?</p> <p>2) In this study ,do both IgG1 and IgG2 mAbs be degenerated when they are analyzed for their HOS status under stressed conditions ? Does the degeneration influence the numerical value of the PCA ELISA ?</p> <p>3) Under what conditions do the reference mAb in triplicate are incubated with?</p> <p>4) Could the author explain the reason why the numerical value of the PCA ELISA of both experimental and reference mAb changed synchronously when they examined the impact of glycation and de-glycosylation, exposure to pH extremes and light exposure on the mAb HOS,and all are in the peak in ab14 (Fig 2A, Fig2B, Fig 2C, Fig 3, Fig 4, Fig5, Fig6)?</p>	
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<b>Minor</b> REVISION comments	The Key words: mAbs and HOS should be deleted	
<b>Optional/General</b> comments	The experiment result in this study obtained under stressed conditions (other than norm conditions ) are less of value in the elucidation of the impact of bioprocess and formulation conditions on the HOS of the mAb. It is important that the biological characteristics of mAbs should be analyzed when they are treated with stressed conditions.	

**Reviewer Details:**

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