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SDI FINAL EVALUATION FORM 1.1

PART 1:

Journal Name:	British Journal of Pharmaceutical Research
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**

PART 2:

FINAL EVALUATOR'S comments on revised paper (if any)	**Authors' response to final evaluator's comments**
1) In this study, both IgG1 and IgG2 mAbs were analyzed for their HOS status mainly under stressed conditions. The experiment result obtained under such stressed conditions (other than norm conditions) are less value in the elucidation of the impact of bioprocess and formulation conditions on the HOS of the mAb.	1) In biologics development, accelerated stress testing (such as the conditions used in this manuscript) is a very common practice and very useful. The main reason is that when a biologics is under development, long term real-time stability (up to 24 months) is not available but regulatory agency (FDA, EMA) will require biologics stability data, therefore the data with accelerated stress testing is provided. The other reason is that it has been shown that the accelerated stress testing outcome is a very good indicative for the biologics actual long term stability. Finally these conditions used are employed by all the biologics developers in their drug development (the conditions used here was suggested by a leading biotech company, top two in the world), thus the results presented in this manuscript is of value to the biologics developers.
2) 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). It is most probable caused by experimental error.	**2)** The purpose of this study is to determine the impact of the various stress conditions on the mAb Higher Order Structure. It is expected that not all areas of the mAb would see significant HOS difference under stress, and the changes detected with the Protein Conformational Array ELISA correlated well with other analytical testing including bioassays. All the data presented was processed statistically with error bars attached, and every experiment was repeated at least two times, therefore the differences detected should not be the results of experimental errors. In addition, numerous biotech companies are using this technology in their biologics development including the majority of the leading biotech and biosimilar developers in the world; the technology has demonstrated its value through the use and acceptance by those customers.