

High Throughput Approach to Antibody Formulation using *i*Formulate® Plates

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OBJECTIVE

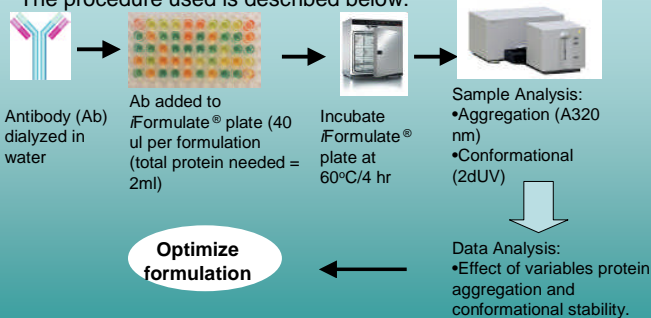
The *i*Formulate® plate provides a pre-designed multivariate formulation kit that evaluates 4 critical formulation variables; pH, ionic strength, stabilizer concentration, and buffer concentration. It consists of 20 unique formulations and a few replicates with a response-surface quadratic design. In this study, the use of this kit for formulation of an antibody is evaluated.

METHODS

The *i*Formulate® design used consisted of the following variables:

- pH (5.0 – 8.0),
- NaCl concentration (0-200 mM),
- Buffer concentration (10-50 mM)
- Trehalose concentration (0-10 wt%).

The procedure used is described below:



RESULTS

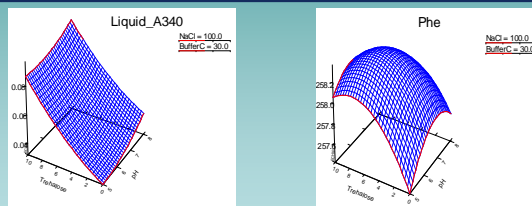


Figure 1. Aggregation and conformational changes correlate.

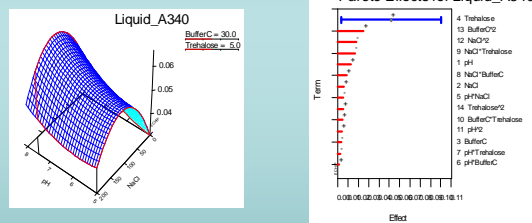


Figure 2. Effect of NaCl on aggregation showing interaction between pH and NaCl

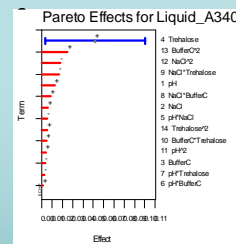


Figure 3. Pareto analysis suggests that trehalose concentration is positively correlated to aggregation of this antibody .

CONCLUSION

1. The results showed that an optimal formulation requires low pH, no trehalose and isotonicity can be adjusted with NaCl
2. *i*Formulate®, a high throughput approach for formulation development that provides maximum number of results with a minimum amount of experimental trials.
3. It saves time, cost and resources for formulation development.
4. *i*Formulate® provides a rationale and justification for the formulation using Quality by Design principles and addresses the newly published FDA guidelines for Process Validation.