



Optimization of a Novel Formulation for mAbdi2 a Biosimilar Monoclonal Antibody



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Poster #: 13

Purpose

Precision in formulation is key to the success of biosimilars, and our motivation stems from the desire to contribute to the advancement of therapeutic biologics through innovative and precise formulation strategies. This study aimed to optimize the formulation for mAbdi2, a promising biosimilar mAb, ensuring its stability and efficacy.

Objective

- To enhance the stability and efficacy of the drug product by optimizing the formulation composition
 - Evaluating the effects of different excipients and additives.
 - Determining the optimal pH and ionic strength levels.
 - Optimizing solubility and tonicity
- To characterize the shelf life and degradation profiles of the formulation.
 - Long-term stability studies under different storage conditions.
 - Freeze-Thaw stability studies.

Methods

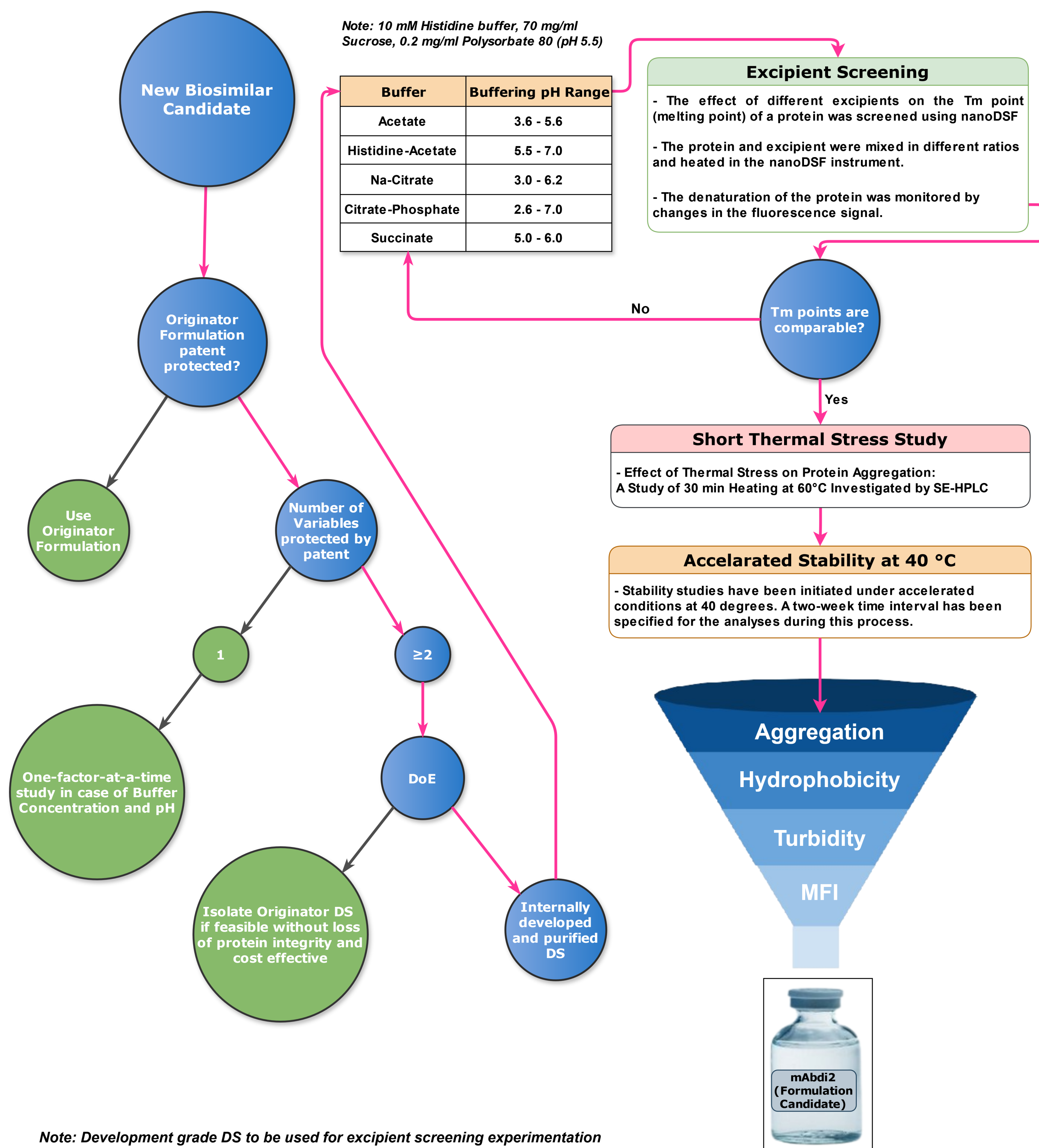


Figure 1: Decision Tree on Biosimilar Formulation Development Strategy

Results

- Large right box above summary

Table 1: Screened excipient effects on mAbdi2 using nanoDSF

Excipients	15 mM Histidine-Acetate (pH 5.0)	20 mM Na-Citrate (pH 5.2)	8 mM Citrate-Phosphate (pH 5.5)	10 mM Acetate (pH 5.2)
Sucrose	+	+	+	+
Mannitol	+	+	+	+
Sorbitol	+	+	+	+
Glycine	+	+	-	+
Arginine	-	-	-	-
NaCl	-	-	-	-
Methionine	+/-	+/-	+/-	+/-
Polysorbate 80	+/-	+/-	+/-	+/-
Poloxamer 188	+/-	+/-	+/-	+/-

+ Stabilization; - Destabilization; +/- No effect

Conclusions

- summary
- outlook

KEY REFERENCES

- [1] first reference
- [2] second reference
- [3] third reference
- [4] Fourth reference
- [5] Fifth reference

ACKNOWLEDGEMENT



We are thankful to Dr. Ali Özüer, Vice President of AbdiBio, and the AbdiBio R&D team for their hard work and excellent scientific and technical support.

MORE INFORMATION



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