

PL5011: Key publications on high-throughput screening of therapeutic protein formulations by light scattering

Summary

This document lists key publications using high-throughput dynamic and static light scattering in formulation development of therapeutic proteins.

Aggregation screening

- High Performance Size Exclusion Chromatography and High-Throughput Dynamic Light Scattering as Orthogonal Methods to Screen for Aggregation and Stability of Monoclonal Antibody Drug Products

Bhirde, A. et al. *J Pharm Sci.* **2020**, 109(11):3330-3339.
<https://doi.org/10.1016/j.xphs.2020.08.013>

- Freeze concentration during freezing: How does the maximally freeze concentrated solution influence protein stability?

Seifert, I. and Friess, W. *Intl. J. Pharmaceutics* **2020** 589:119810
<https://doi.org/10.1016/j.ijpharm.2020.119810>

- High Throughput Formulation Screening for Global Aggregation Behaviors of Three Monoclonal Antibodies

Li, Y., Mach, H. and Blue, J.T. *J. Pharm. Sci.* **2011** 100(6):2120-2135
<https://doi.org/10.1002/jps.22450>

Excipient effects

- Orthogonal Techniques to Study the Effect of pH, Sucrose, and Arginine Salts on Monoclonal Antibody Physical Stability and Aggregation During Long-Term Storage

Svilenov, H. et al. *J Pharm Sci.* **2020**, 109(1):584-594.
<https://doi.org/10.1016/j.xphs.2019.10.065>

- Effects of Ionic Strength and Sugars on the Aggregation Propensity of Monoclonal Antibodies: Influence of Colloidal and Conformational Stabilities

Saito, S. et al. *Pharm. Res.* **2013** 30:1263-1280
<https://doi.org/10.1007/s11095-012-0965-4>

Colloidal interaction measurements (k_D , A_2)

- Assessment of net charge and protein-protein interactions of different monoclonal antibodies

Lehermayr, C. et al. *J Pharm Sci.* **2011**, 100(7):2551-2562.
<https://doi.org/10.1021/acs.molpharmaceut.9b00852>

- The missing piece in the puzzle: Prediction of aggregation via the protein-protein interaction parameter A_2^*

Koepf, E. et al. *Eur J Pharm Biopharm.* **2018**, 128:200-209.
<https://doi.org/10.1016/j.ejpb.2018.04.024>

- High-Throughput Assessment of Thermal and Colloidal Stability Parameters for Monoclonal Antibody Formulations

He, F. et al. *J. Pharm. Sci.* **2011** 100(12):516-5141
<https://doi.org/10.1002/jps.22712>

- High-Throughput Screening for Colloidal Stability of Peptide Formulations Using Dynamic and Static Light Scattering

Dauer, K. et al. *Mol. Pharmaceutics* **2021**
<https://doi.org/10.1021/acs.molpharmaceut.0c01028>

- Solubility Challenges in High Concentration Monoclonal Antibody Formulations: Relationship with Amino Acid Sequence and Intermolecular Interactions

Pindrus, M. et al. *Mol. Pharmaceutics* **2015** 12911):3896-3907
<https://doi.org/10.1021/acs.molpharmaceut.5b00336>

- Weak Interactions Govern the Viscosity of Concentrated Antibody Solutions: High-Throughput Analysis Using the Diffusion Interaction Parameter

Connolly, B.D. et al. *Biophys. J.* **2012** 103(1):69-78
<https://doi.org/10.1016/j.bpj.2012.04.047>

Temperature ramps

- Temperature-ramped studies on the aggregation, unfolding, and interaction of a therapeutic monoclonal antibody

Menzen, T. and Friess, W. *J Pharm Sci.* **2014**, 103(2):445-455.
<https://doi.org/10.1002/jps.23827>

Novel approaches to evaluating physical stability

- A new approach to study the physical stability of monoclonal antibody formulations – dilution from a denaturant

Svilenov, H. et al. *J Pharm Sci.* **2018**, 107(12):3007-3013.
<https://doi.org/10.1016/j.xphs.2018.08.004>

- Advancing therapeutic protein discovery and development through comprehensive computational and biophysical characterization

Gentiluomo, L. et al. *Mol Pharmaceutics*. **2020**, 17(2):426-440.
<https://doi.org/10.1021/acs.molpharmaceut.9b00852>

- In silico prediction of diffusion interaction parameter (k_D), a key indicator of antibody solution behaviors

Tomar, D.S. et al. *Pharm Res.* **2018**, 35(10):193.
<https://doi.org/10.1007/s11095-018-2466-6>

- A single molecular descriptor to predict solution behavior of therapeutic antibodies

Kingsbury, J.S. et al. *Sci. Adv.* **2020**, 6(32).
<https://doi.org/10.1126/sciadv.abb0372>

- Formulations That Suppress Aggregation During Long-Term Storage of a Bispecific Antibody are Characterized by High Refoldability and Colloidal Stability

Svilenov, H. and Winter, G. *J Pharm Sci.* **2020**, 109(6):2048:2058.
<https://doi.org/10.1016/j.xphs.2020.03.011>

Reversible self-association

- The Influence of Charge Distribution on Self-Association and Viscosity Behavior of Monoclonal Antibody Solutions

Yadav, S. et al. *Mol. Pharmaceutics* **2012** 9(4):791-802
<https://doi.org/10.1021/mp200566k>

- A systematic multitechnique approach for detection and characterization of reversible self-association during formulation development of therapeutic antibodies

Esfandiary, R. et al. *J. Pharm. Sci.* **2013** 102(9):3089-3099
<https://doi.org/10.1002/jps.23654>

- Mechanism of Reversible Self-Association of a Monoclonal Antibody: Role of Electrostatic and Hydrophobic Interactions

Esfandiary, R. et al. *J. Pharm. Sci.* **2015** 104(2):577-586

<https://doi.org/10.1002/jps.24237>

Viscosity screening by DLS

- Screening of monoclonal antibody formulations based on high-throughput thermostability and viscosity measurements: Design of experiment and statistical analysis

He, F. et al. *J. Pharm. Sci.* **2010** 100(4):1330-1340

<https://doi.org/10.1002/jps.22384>

- Effect of Sugar Molecules on the Viscosity of High Concentration Monoclonal Antibody Solutions

He, F. et al. *Pharm. Res.* **2011** 28:1552-1560

<https://doi.org/10.1007/s11095-011-0388-7>

Beyond mAbs

- Viscosities and Protein Interactions of Bispecific Antibodies and Their Monospecific Mixtures

Woldeyes, M.A. et al. *Mol. Pharmaceutics* **2018** 15910):4745-4755

<https://doi.org/10.1021/acs.molpharmaceut.8b00706>

- Resolving Liquid-Liquid Phase Separation for a Peptide Fused Monoclonal Antibody by Formulation Optimization

Qi, W. et al. *J. Pharm. Sci.* **2021** 110(2):738-745

<https://doi.org/10.1016/j.xphs.2020.09.020>



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