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Small-Angle Neutron Scattering study of the NIST mAb reference material MARIA MONICA CASTELLANOS, NIST Center for Neutron Research, IBBR, YUN LIU, NIST Center for Neutron Research, Univ. Delaware, SUSAN KRUEGER, JOSEPH CURTIS, NIST Center for Neutron Research — Monoclonal antibodies (mAbs) are of great interest to the biopharmaceutical industry because they can be engineered to target specific antigens. Due to their importance, the biomanufacturing initiative at NIST is developing an IgG1 mAb reference material ‘NIST mAb’, which can be used by industry, academia, and regulatory authorities. As part of this collaborative effort, we aim at characterizing the reference material using neutron scattering techniques. We have studied the small-angle scattering profile of the NIST mAb in a histidine buffer at 0 and 150 mM NaCl. Using Monte Carlo simulations, we generate an ensemble of structures and calculate their theoretical scattering profile, which can be directly compared with experimental data. Moreover, we analyze the structure factor to understand the effect of solution conditions on the protein-protein interactions. Finally, we have measured the solution scattering of the NIST mAb, while simultaneously performing freeze/thaw cycles, in order to investigate if the solution structure was affected upon freezing. The results from neutron scattering not only support the development of the reference material, but also provide insights on its stability and guide efforts for its development under different formulations.

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