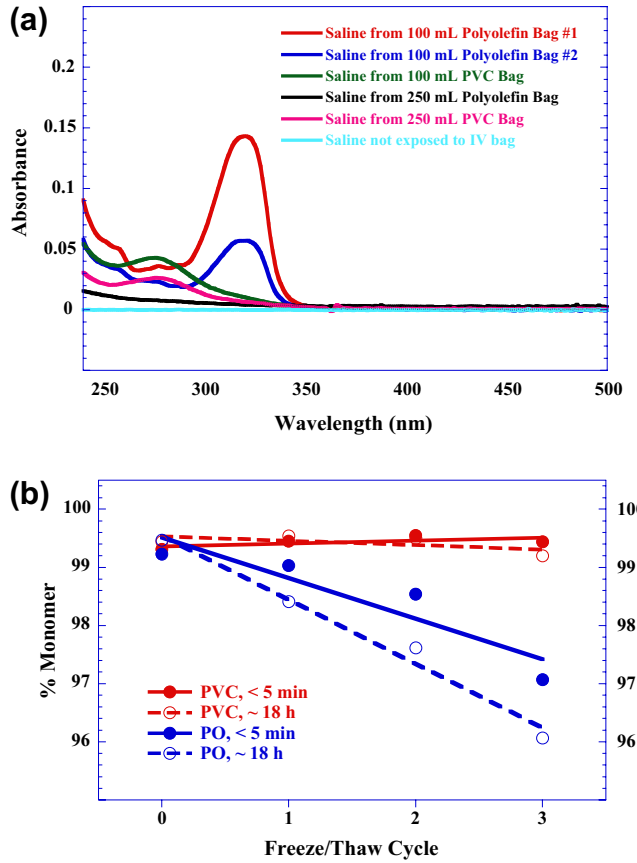

Figure 5.1 (a) Comparison of the absorbance of saline solutions from different intravenous (IV) administration infusion bags. (b) Stability of dulanermin in 100 mL IV infusion bags and the effect of freezing and thawing. Dulanermin was diluted into 100 mL IV bags to a final concentration of 0.08 mg/mL and then removed for analysis immediately or after 16 h.
From Chang et al. (2010).

holds the homotrimer together (referred to as the monomer) and when incubated with a compound capable of removing the zinc resulted in an instability when the protein was subjected to the stress of freezing and thawing.

The degradation of a mAb stored in IV bags due to exposure of leachates has not been well documented in the literature. However, metal ion leaching from IV bags can occur, and it has been shown that IgG2 mAb not stored in IV bags can undergo subtle changes in tertiary structure when exposed to Fe (III) ions (Zhou et al., 2010). The ions may promote oxidation reactions, which in turn impacts the physical stability of the antibody. In particular it was shown that potential aggregation-prone regions and hydrophobic patches in the IgG2 mAb are in close proximity to amino acid residues whose binding with metal ions leads to oxidation and aggregation (Kumar, Zhou, & Singh, 2014). In addition, two studies have been published purporting to show that