



Figure 5.2 Comparison of disassembled components of 100 and 250 mL polyolefin (PO) bags from the same manufacturer.

Adapted from [Chang et al. \(2010\)](#).

there was no stability impact to the mAbs tested after dilution into PVC bags ([Ikesue, Vermeulen, Hoke, & Kolesar, 2010](#); [Parti & Mankariou, 1997](#)).

mAb aggregation and particulate formation during IV administration

Although leachates from IV bags can impact the stability as well as safety of a mAb prepared for IV administration, the simple process of dilution into a bag with suitable IV administration fluid can have serious consequences. The excipients used to create a robust and stable formulation in a vial are diluted, as is the mAb. Surfactants that have been added to prevent adsorption to surfaces and generation of aggregates of mAb at the air–water interfaces may decrease below the necessary concentration for effectiveness. Often when proteins adsorb to solid surfaces they undergo an unfolding on the surface, and after release into the solution, contribute to aggregate and particulate formation