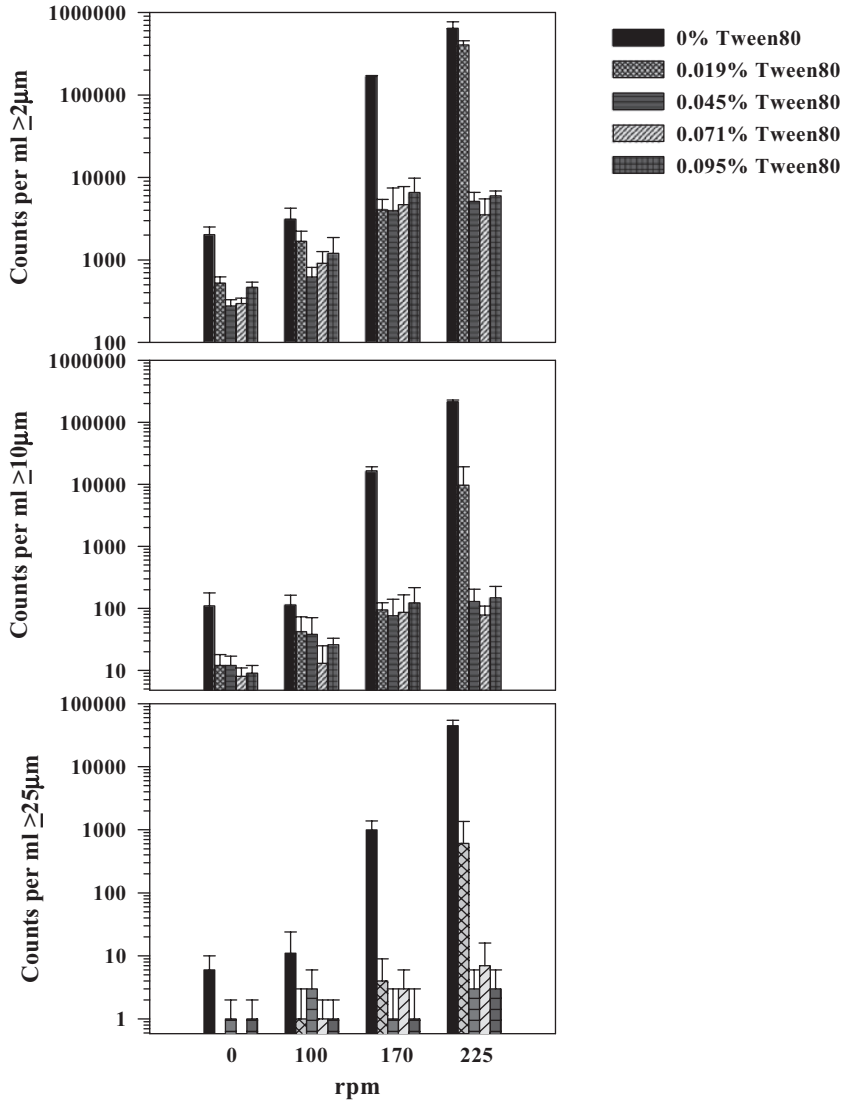

Figure 8-7 Effect of Tween 80 concentration on particle formation in solutions of recombinant human hemoglobin as a function of shear stress. *Source*: From Ref. 46.

sodium dodecyl sulfate—also protected the protein from denaturation although these surfactants have not yet been approved for use in injectable formulations. The authors pointed out that surfactants may be needed to protect proteins from denaturation during the freezing step only, and that other stabilizers, for example, sucrose, may be needed to further protect the protein during freeze drying.

Surfactants were ineffective in preventing BST aggregation and precipitation in solution at elevated temperature[1], whereas other stabilizers such as sucrose were more effective (45). Tween 80 was more effective in reducing the amount of measurable particles due to aggregation of recombinant human hemoglobin (Fig. 8-7).

[1] While polysorbate 80 was not effective in stabilizing BST at elevated temperature, it was effective when the applied stress was agitation. Also, the authors noted that polysorbate 80 destabilization of BST was not observed at ambient or refrigerated temperatures as other decomposition pathways, for example, deamidation, became more predominant at lower temperatures.