



These results contribute to the general understanding of the protein adsorption to IV infusion filters and allow the design of more efficient compatibility studies” Besheer (2017).

Abstract:

Ensuring compatibility of administered therapeutic proteins with IV administration sets is an important regulatory requirement. A low dose-recovery during administration of low protein concentrations is among the commonly observed incompatibilities, and it is mainly due to adsorption to in-line filters.

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To better understand this phenomenon, we studied the adsorption of 4 different therapeutic proteins (2 IgG1s, 1 IgG4 and 1 Fc Fusion protein) diluted to 0.01 mg/mL in 5% glucose or 0.9% NaCl solutions to 8 in-line filters (5 positively charged and 3 neutral filters made of different polymers and by different suppliers). The results show certain patterns of protein adsorption, which depend to a large extent on the dilution solution and the filter material, and to a much lower extent on the proteins’ biophysical properties. Investigation of the filter membranes’ zeta potential showed a correlation between the observed adsorption pattern in 5% glucose solution and the filter’s surface charge, with higher protein adsorption for the

strongly negatively charged membranes. In 0.9% NaCl solution, the surface charges are masked, leading to different adsorption pattern. These results contribute to the general understanding of the protein adsorption to IV infusion filters and allow the design of more efficient compatibility studies.

Reference;

Besheer, A. (2017) Protein adsorption to in-line filters of intravenous administration sets. Journal of Pharmaceutical Sciences. May 27th. .

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