In this study, we determined the subvisible particle levels in IV solutions and after the solutions were processed with an IV administration setup that mimicked the typical clinical method of administration" Pardeshi et al (2016).

Abstract:

Intravenous (IV) infusion is used for administration of a large proportion of biologic therapeutics, including most monoclonal antibody products. In this study, we determined the subvisible particle levels in IV solutions and after the solutions were processed with an IV administration setup that mimicked the typical clinical method of administration. IV saline in bags manufactured by both Hospira and Baxter contained 1600-8000 microparticles/mL and 4-73 × 106 nanoparticles/mL in solution. When IV immunoglobulin was diluted into the IV saline, 3700-23,000 microparticles/mL and 18-240 × 106 nanoparticles/mL were detected. During processing of the solution through the IV system, in-line filters removed most microparticles. However, there were still 1-21 × 106 nanoparticles/mL in IV saline and 7-83 × 106 nanoparticles/mL in IV immunoglobulin diluted in saline.

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Finally, in samples processed through in-line filters, we found relatively large microparticles (20-60 μm) that were composed of protein or polycarbonate. These particles resulted from shedding of polycarbonate and sloughing off of protein films downstream from the filter membrane. Overall, the results document that even with in-line filters in place, high levels of subvisible particles are delivered to patients and there is a need for improved, more effective filters and IV solutions with lower particle levels.

Reference:

Pardeshi, N.N., Qi, W., Dahl, K., Caplan, L. and Carpenter, J.F. (2016) Microparticles and Nanoparticles Delivered in Intravenous Saline and in an Intravenous Solution of a

Therapeutic Antibody Product. Journal of Pharmaceutical Sciences. November 7th. .

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