

## Recent publications

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### **An exploratory study on the effect of mechanical stress on particle formation in monoclonal antibody infusions**

Mona Abdel-Tawab<sup>1,2</sup> \* | Srijib Banerjee<sup>3</sup> | Roland Kirchner<sup>3</sup> | Thomas Wellenhofer<sup>4</sup> | Lukas Hahn<sup>5</sup> | Lorenz Meinel<sup>5</sup> | Ulrike Holzgrabe<sup>5</sup> | Manfred Schubert-Zsilavecz<sup>2</sup> | Andreas Seidl<sup>3</sup> | Franz Stadler<sup>6</sup>

<sup>1</sup>Central Laboratory of German Pharmacists, Eschborn, Germany

<sup>2</sup>Institute for Pharmaceutical Chemistry, Johann-Wolfgang-Goethe University, Frankfurt, Germany

<sup>3</sup>Leukocare AG, Munich, Germany

<sup>4</sup>Bahnhof Pharmacy, Freilassing, Germany

<sup>5</sup>Institute for Pharmacy and Food Chemistry, Julius-Maximilian University, Würzburg, Germany

<sup>6</sup>Foundation for Drug Safety, Munich, Germany

[\\*m.tawab@zentrallabor.com](mailto:m.tawab@zentrallabor.com)

Monoclonal antibody infusions (mAb-i) are administered for the treatment of various diseases. They are often transported over long distances from the compounding site to the site of administration. However, transport studies are typically carried out with the original drug product but not with compounded mAb-i. To address this gap, the impact of mechanical stress on the formation of subvisible/nanoparticles in mAb-i was investigated by dynamic light scattering and flow imaging microscopy. Different mAb-i concentrations were subjected to vibrational orbital shaking and stored at 2–8°C up to 35 days. The screening revealed that pembrolizumab and bevacizumab infusions show the highest propensity for particle formation. Especially bevacizumab at low concentrations exhibited an increase in particle formation. Because of the unknown health risks associated with the long-term application of subvisible particles (SVPs)/ nanoparticles in infusion bags, stability studies carried out in the frame of licensing application procedures should also focus on SVP formation in mAb-i. In general, pharmacists should minimize the time of storage and mechanical stress during transport, especially in the case of low-concentrated mAb-i. Moreover, if siliconized syringes are used, they should be washed once with saline solution to minimize particle entry.