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Impact of Magnetic Stirring on Stainless Steel Integrity

- Effect on Biopharmaceutical Processing

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ABSTRACT

Stainless steel containers are widely used in the pharmaceutical and biopharmaceutical industry for the storage of buffers, process intermediates, and purified drug substance. They are generally held to be corrosion resistant, biocompatible, and non-reactive, although it is well established that trace amounts of metal ions can leach from stainless steel equipment into biopharmaceutical products. We report here that the use of stainless steel containers in conjunction with magnetic stirring bars leads to significantly aggravated metal contamination, consisting both of metal particles and significantly elevated metal ions in solution, the degree of which is several orders of magnitude higher than described for static conditions. Metal particles are analyzed by scanning electron microscopy with electron dispersive X-ray spectroscopy, and metal content in solution is quantitated at different time points by inductively coupled plasma - mass spectrometry. The concentration of iron, chromium, nickel, and manganese

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