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Role of mass spectrometry in packaging innovation and solution

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The vial and syringe performance is screened with pharmaceutically relevant formulation conditions. The influence of pH, buffer type, ionic strength, and glass type and source is evaluated. In addition, an aggressive but discriminating formulation condition (pH 11) is used to ascertain the impact of syringe processing. Advanced analytical tools including inductively coupled plasma/ mass spectrometry, scanning electron microscopy, atomic force microscopy, and dynamic secondary ion mass spectroscopy showed significant differences in glass performance between vials and syringes. Pre-filled syringes outperform vials for most tests and conditions. The manufacturing conditions for vials lead to glass defects, not found in pre-filled syringes, which result in a less chemically resistant surface. The screening methodology presented in this work can be applied to assess suitability of primary containers for specific drug applications.

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