A Method to Determine the Kinetics of Sulute Mixing in Liquid/Liquid Formulation Dual-Chamber Syringes

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Dual-chamber syringes were originally designed to separate a solid substance and its diluent. However, they can also be used to separate liquid formulations of two individual drug products, which cannot be co-formulated due to technical or regulatory issues. A liquid/liquid dual-chamber syringe can be designed to achieve homogenization and mixing of both solutions prior to administration, or it can be used to sequentially inject both solutions. While sequential injection can be easily achieved by a dual-chamber syringe with a bypass located at the needle end of the syringe barrel, mixing of the two fluids may provide more challenges. Within this study, the mixing behavior of surrogate solutions in different dual-chamber syringes is assessed. Furthermore, the influence of parameters such as injection angle, injection speed, agitation, and sample viscosity were studied. It was noted that mixing was poor for the commercial dual-chamber syringes (with a bypass designed as a longitudinal ridge) when the two liquids significantly differ in their physical properties (viscosity, density). However, an optimized dual-chamber syringe design with multiple bypass channels resulted in improved mixing of liquids. LAY ABSTRACT: Dual-chamber syringes were originally designed to separate a solid substance and its diluent. However, they can also be used to separate liquid formulations of two individual drug products. A liquid/liquid dual-chamber syringe can be designed to achieve homogenization and mixing of both solutions prior to administration, or it can be used to sequentially inject both solutions. While sequential injection can be easily achieved by a dual-chamber syringe with a bypass located at the needle end of the syringe barrel, mixing of the two fluids may provide more challenges. Within this study, the mixing behavior of surrogate solutions in different dual-chamber syringes is assessed. Furthermore, the influence of parameters such as injection angle, injection speed, agitation, and sample viscosity were studied. It was noted that mixing was poor for the commercially available dual-chamber syringes when the two liquids significantly differ in viscosity and density. However, an optimized dual-chamber syringe design resulted in improved mixing of liquids.
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