

# Validation of a procedure to mix homogenous solutions in bags and syringes

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## Abstract

**Objectives:** It is essential to obtain homogeneous drug mixtures, especially when only a fraction of the prepared dose is to be administered. This study aimed to validate a manual mixing method for guaranteeing homogeneity.

**Methods:** One operator tested six standardised manual mixing techniques (one, five and 10 inversions, and one, five and 10 bottoms-up agitations) six times each for preparations in bags and syringes. The mixing step was reproduced experimentally by adding a small volume of analyte (0.8 mL for syringes and 6 mL for bags) to a large volume of matrix (50 mL for syringes and 300 mL for bags). Three analyte/matrix pairings were tested: water/water, water/glucose 20% and glucose 20%/water. The tracer (sodium chloride) was assayed using capillary electrophoresis. Volume measurement errors were corrected by weighing bags and syringes. In order to evaluate inter-individual variability, the 10 inversions technique was tested by 10 drug preparation technicians. Mixtures were considered acceptable if they were between 95% and 105% accurate and if the coefficient of variation was  $\leq 5\%$  of the average of the six repetitions.

**Results:** Both the 10 inversions and 10 bottoms-up agitations mixing techniques ensured acceptable mixtures by the principal technician in all tested conditions. When mixing using the 10 inversions method was tested by the 10 technicians, the mixture's mean acceptability could no longer be ensured.

**Conclusion:** Use of a standardised mixing technique did not appear to be sufficient to obtain a homogeneous mixture across technicians. Standardised guidelines for needle position, needle rinsing and speed of addition should be implemented.

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