Qualification and Performance Evaluation of an Automated System for Compounding Injectable Cytotoxic Drugs

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Abstract

Obectives: Use of automated systems for the production of chemotherapy will increase in answer to hospitals' needs to rationalise production. The aim of the study was to evaluate the performance of a PharmaHelp® automate system for compounding chemotherapy.

Methods: Viable and non viable particles in air and liquid were measured by particle counter. Surface chemical contamination was simulated with a quinine solution. Microbiological contamination and aseptic processes were studied using media-fill tests. Dose accuracy was evaluated using a gravimetric method, in simulation studies and with real products in daily practice. Productivity was calculated by batch of ten IV-bags.

Results: No particles or microbiological contamination were detected. Filling was accurate for all the volumes of non-viscous solution studied (97–103 %). Minimum volumes which could be prepared accurately were 2 mL and 5 mL for the non-viscous and viscous solutions, respectively. For 2–5 mL volumes, the robot was less accurate than average, and 0–2% of bags were rejected (deviation > 10%). Average fill deviations were from 0–3% for 2–5 mL volumes and < 1% for volumes above 5 mL. Average production time for ten bags was 61 ± 11 min.
Conclusions: The automated system was able to produce chemotherapy effectively, delivering appropriate quality with productivity comparable to manual preparations. These results confirmed that such automated systems have the potential to guarantee optimal safety for patients and technicians.

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