# Cytotoxics compounded sterile preparation control by HPLC during a 16-month assessment in a French university hospital: importance of the mixing bags step




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| Résumé en anglais | The Centralized Chemotherapy Reconstitution Unit (CCRU) of Paul Brousse Hospital Pharmacy Department assessed the reliability of its Cytotoxics Compounded Sterile Products (CCSP) preparation method in order to improve its CCSP quality assurance system. Five cytotoxic drugs — gemcitabine, 5-fluorouracil, docetaxel, paclitaxel, and oxaliplatin — were assayed by high performance liquid chromatography (HPLC) to determine CCSP concentration. During the observation period, 23,892 CCSP were prepared. Overall, 12,964 preparations contained one of the five analyzed drugs; 7382 (56.9%) out of 12,964 CCSP were analyzed by HPLC; 646 (8.8%) out of 7382 concentrations were outside ± 20% of the prescribed dose; 544 (84.2%) out of 646 were post-administration results and could not be verified. Out of 102 (15.8%) pre-administration results that were re-tested after re-shaking, 94 (92.2%) were found to be acceptable upon re-testing, and 8 (7.8%) were confirmed to be unacceptable and needed to be re-compounded. The 8.8% of tested CCSP were outside ± 20% of the prescribed dose, but extrapolating the results on re-tested CCSP, we can say that our CCSP preparation is reliable with an estimation of only 0.7% of 7382 CCSP analyzed, confirmed as being ± 20% outside the prescribed dose. Nevertheless, this ± 20% magnitude of error should be reduced. Based on pre-administration results, the primary cause of concentration errors appeared to be insufficient mixing of the finished product. Most CCSP dosages occurred after it had been administered, the organization should, therefore, be improved to include testing all CCSP prior to administration. Pharmaceutical companies should endeavor to manufacture compounded injectible drugs in a ‘ready to use’ form and provide vehicles in accurate volumes in order to improve compounding precision. |

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