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Development and validation of an analytical method to quantify cytotoxic drugs in gauze dressings used in luer-lock connection systems for a safer preparation

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Abstract

Background: Despite patient's benefits, healthcare professionals face occupational hazardous when handling cytotoxic drugs used for cancer treatment [1]. Several organizations outline procedures, conditions, and equipment recommended for safe handling. The International Society of Oncology Pharmacy Practice (ISOPP) standards [2] are the guidelines recommended by the European Parliament but, unlike others (e.g. Occupational Safety and Health Administration (OSHA)) [3], they omit the recommendation of using dressings at luer-lock connections to contain cytotoxic leaks. **Objective:** This study aims to develop and validate an analytical method for cyclophosphamide (CP) and 5-fluorouracil (5-FU) identification and quantification in gauze dressings for monitoring real-life occupational situations. **Methods:** Gauze dressings (20x10 cm) containing varying concentrations of CP and 5-FU were placed in 15 mL falcon tubes containing acetonitrile:methanol:water (19:13:68). After stirring, the samples were filtered through a 0.22 µm filter and analyzed using HPLC-DAD, equipped with a C18 column (Hypersil Gold™ 150mm x 4.6mm and 5µm particle size). The mobile phases employed were acetonitrile:methanol:water (19:13:68) (CP) and 0.5% acetic acid in water (for 5-FU), with detection set at 205 nm (CP) and 260 nm (5-FU). **Results:** The mean of five calibration curves was calculated for each drug, each exhibiting $R^2 > 0.997$, confirming the linearity for both drugs. Regarding sensitivity, LOD of 0.006 µg/cm² (5-FU) and 0.11 µg/cm² (CP) and LOQs of 0.02 µg/cm² (5-FU) and 0.32 µg/cm² (CP), were obtained. Accuracy ranged between 93%-110%, while precision ranged between 91%-99%. At room temperature, gauze dressings deliberately contaminated exhibited superior stability for 5-FU compared to CP. **Conclusions:** The method has been successfully validated for analyzing CP and 5-FU residues in gauze, meeting essential validation criteria. Upon suitability verification, the method will be applicable for the evaluation of the importance of using gauze dressing when handling cytotoxic drugs, by assessing contaminations occurring during their real-life handling routine.

Keywords: cytotoxic drugs; occupational hazardous; chemotherapy; HPLC-DAD

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