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Professor Doutor Pedro Rodrigues

ijup@reit.up.pt

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21819 | Development and validation of an analytical method to assess the importance of using gauze dressings in luer-lock connection systems during the preparation of cytotoxic drugs

Clara Silva[1]; Helena Carmo[1]; Vânia Oliveira[2,3]; Daniel Carvalho[4]; Fernando Moreira[2,5]

UCIBIO, Laboratory of Toxicology, Department of Biological Sciences, Faculty of Pharmacy, University of Porto, Porto, Portugal[1]; ESS, Polytechnic of Porto, Porto, Portugal[2]; Unidade Local de Saúde de Entre Douro e Vouga (ULSEDV), Santa Maria da Feira, Portugal[3]; i3S - Instituto de Investigação e Inovação em Saúde, Universidade do Porto, Portugal[4]; REQUIMTE/LAQV, ESS, Polytechnic of Porto, Porto, Portugal[5]

Background & Aim: Healthcare professionals face occupational hazardous when handling cytotoxic drugs used for cancer treatment [1]. The International Society of Oncology Pharmacy Practice (ISOPP) standards [2] are the guidelines recommended by the European Parliament for safety procedures but, unlike others (e.g. Occupational Safety and Health Administration (OSHA)) [3], fail to mention the need to use dressings at luer-lock connections to contain cytotoxic leaks. This study aims to develop and validate an analytical method capable of identifying and quantifying cyclophosphamide (CP) and 5-fluorouracil (5-FU) in gauze dressings. **Methods:** Gauze dressings (20x10 cm) containing varying concentrations of CP and 5-FU were placed in 15 mL falcons containing acetonitrile:methanol:water (19:13:68). After stirring, the samples were passed through a 0.22 µm filter. The extracted samples were then 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 (5-FU) and detection was set at 205 nm (CP) and 260 nm (5-FU). **Results:** The mean of five calibration curves generated for each drug were calculated, each exhibiting $R^2 > 0.997$, thus confirming the linearity for both drugs. Regarding sensitivity, LOD of 0.006 µg/cm^2 for 5-FU and 0.11 µg/cm^2 for CP and LOQs of 0.02 µg/cm^2 for 5-FU and 0.32 µg/cm^2 for CP, were obtained. Accuracy fell within the range of 93%-110% and precision was set between 91% and 99%. At room temperature, gauze dressings deliberately contaminated exhibited superior stability for 5-FU compared to CP. **Conclusions:** The method has been successfully validated and, once suitability is confirmed, it will be applicable for the evaluation of the importance of using gauze dressing when handling cytotoxic drugs, by testing contaminations occurring during real-life routine handling of these cytotoxic drugs.

Keywords: Cytotoxic Drugs, Occupational Hazardous, Chemotherapy, HPLC-DAD.

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