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Development and implementation of a gravimetric control method for chemotherapeutic preparations

Desenvolvimento e aplicação de um método de controlo gravimétrico de preparações quimioterápicas

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Introduction: The complexity of antineoplastic preparation increases the risk of errors, thus demanding robust safety systems. Common methods to prevent errors committed during aseptic preparation include double visual verification and gravimetric control (GC), in which the mass of each preparation is determined to ensure product accuracy. The aim of this work is to develop a GC that routinely, quickly, and simply enables quality control of antineoplastic preparations in the Centro Hospitalar de Baixo Vouga (CHBV) hospital unit.

Methods: A cross-sectional descriptive observational study was carried out in the CHBV chemotherapy preparation unit over four days in February and March 2024, analyzing 122 chemotherapy preparations. Data was collected by observing the compounding process of preparations in different containers: bags, syringes or pumps. The study focused on weighing the masses of the intermediate and final products using a semi-analytical precision scale. The variables under study were the masses of the containers (pre-addition, post-addition and post-infusion of the drug and diluent, in the case of the pumps), the volume of the drug measured, the diluent used, the volume of the diluent, the operator and the date of preparation. The density of the commercially available ready-to-use drugs or resuspended drugs was determined after evaluation of three samples of each included drug. A deviation of up to 5% of the density of each drug, determined by calculating the variation coefficient, was considered acceptable. A semi-automatic calculation model using Microsoft Excel® was developed to allow gravimetric control of the preparations. Once the method had been created, an applicability test was carried out.

Results and Discussion: The study reveals minimal variability in drug density, with coefficients of variation of less than 5%, indicating consistent accuracy between commercially available drugs. This consistency, suggests the adequacy of the implementation of a GC method. A semi-automated system for quality control of chemotherapy preparations has been developed, designed to be practical and adaptable to use with both syringes and bags/pumps. The main limitation of the method developed is the need to confirm the masses of the containers used. Compared to most of the evaluated drugs, there is a greater diversity of laboratories producing containers and even between different batches from the same producer, the possibility of weight variation cannot be ruled out. Nevertheless, the method developed allows for the possibility of editing the container's mass, enabling its adaptation. During the performance of the applicability test, it was possibly to quickly calculate the percentage error of each preparation, and intuitively verify the validity of the preparation by means of a color-based code. In view of the results observed, the 53 preparations evaluated were presumably prepared correctly, with a variation of between 0% and 4.30%.

Conclusion: The developed method is functional, practical, and versatile, allowing healthcare professionals to perform quality control of chemotherapy preparations using either syringes or bags/pumps. By implementing this methodology, hospital units will be able to prevent overdoses that could put patients at risk, or underdoses that could jeopardize compliance with the prescribed therapy.

Keywords: Antineoplastic preparation; Gravimetric control; Quality control; Aseptic technique; Oncology pharmacy; Chemotherapy.
Palavras-chave: Preparação antineoplásica; Controlo gravimétrico; Controlo de qualidade; Técnica assética; Farmácia oncológica; Quimioterapia.