inclusIV compounding portfolio

June 2025

KIRO® Oncology dosing accuracy results

Dosing accuracy specifications for the preparation of compounded sterile preparations (CSPs) in the KIRO® Oncology pharmacy compounding device (PCD) have been validated to be ±5% for dosing volumes above 1 mL and reconstitution volumes above 2 mL. Under exceptional circumstances, the dosing accuracy may be outside this specification for a limited number of preparations, only a 0,35%, due to the different geometries of the rubber stoppers of the different types of drug vials. In these cases, the gravimetric control system within KIRO® Oncology will identify this dosing accuracy deviation and will require a pharmacist to determine if the preparation may be released or not for administration.

This document presents real production data of preparations that were compounded in 2 European hospitals using KIRO® Oncology. Compounding data of 13,120 preparations, including 23 oncology drugs, were analyzed and 99.65% of the preparations were within ±5% dosing accuracy limits. Only 0.35% of them were not within ±5% dosing accuracy limits (See Figure 1) and all preparations were within ±10% dosing accuracy limits recommended for a pharmacist to release preparations when appropriate. In addition, 452 cyclophosphamide advanced reconstitution vials were prepared in KIRO® Oncology and the dosing accuracy for the added diluent was within ±5% reconstitution accuracy limits for all vials.

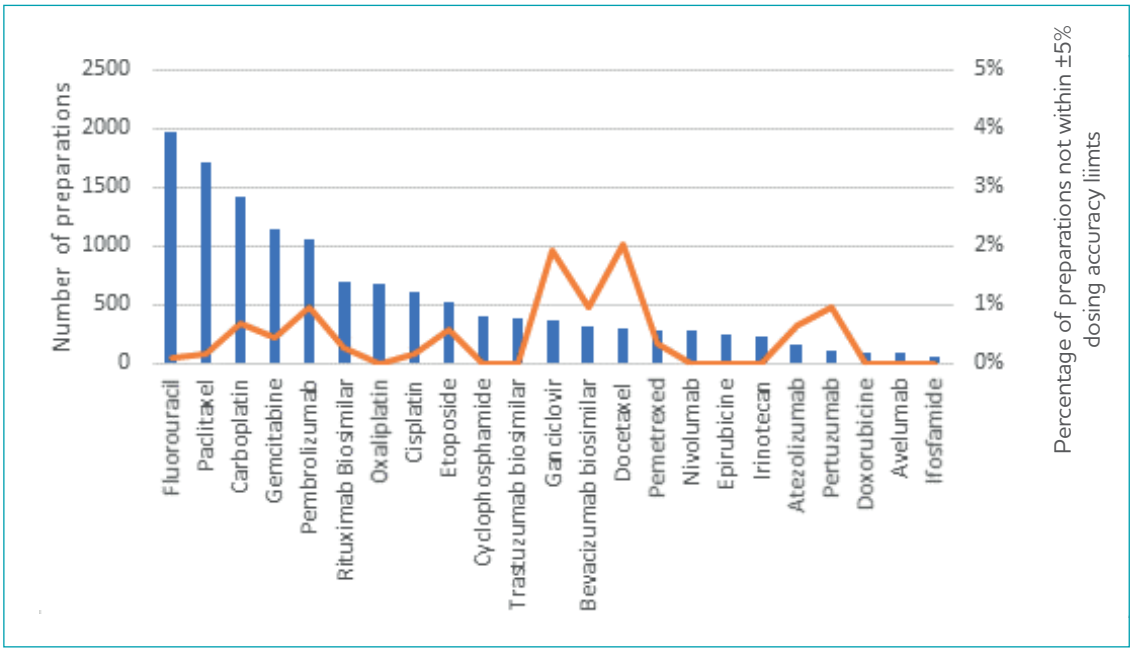

Figure 1. Number of preparations per drug compounded in KIRO® Oncology and percentage of preparations not within ±5% dosing accuracy limit.

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Statistical significance of the presented data is supported by the high number of preparations for different drug groups. **Group A**, more than 459 preparations per drug for 99% reliability and 99% confidence level, and **group B**, more than 59 preparations per drug for 95% reliability and 95% confidence level, being 459 and 59 the sample sizes calculated based on a binomial distribution model with zero failures for the indicated confidence level and reliability values. See group A in **Table 1**, and group B in **Table 2**:

Table 1. Group A.

Drug	Preparations	Not within ±5%	Mean dosing accuracy	SD
Fluorouracil	1972	0.10%	-0.29%	1.59%
Paclitaxel	1720	0.17%	0.20%	1.44%
Carboplatin	1426	0.07%	-0.02%	1.32%
Gemcitabine	1151	0.43%	0.88%	1.70%
Pembrolizumab	1051	0.95%	0.15%	1.33%
Rituximab Biosimilar	695	0.29%	-0.17%	4.76%
Oxaliplatin	670	0.00%	-0.30%	1.60%
Cisplatin	607	0.16%	-0.46%	3.66%
Etoposide	520	0.58%	0.12%	1.34%
TOTAL	9812	0.27%	0.03%	2.12%

Table 2. Group B.

Drug	Preparations	Not within ±5%	Mean dosing accuracy	SD
Cyclophosphamide	406	0.00%	0.20%	1.40%
Trastuzumab biosimilar	388	0.00%	0.13%	1.32%
Ganciclovir	364	1.92%	-0.16%	1.50%
Bevacizumab biosimilar	316	0.95%	-0.09%	0.51%
Docetaxel	294	2.04%	0.19%	1.34%
Pemetrexed	290	0.34%	0.04%	1.28%
Nivolumab	285	0.00%	-0.31%	5.64%
Epirubicin	243	0.00%	0.10%	1.30%
Irinotecan	224	0.00%	-0.31%	1.38%
Atezolizumab	154	0.64%	0.19%	1.27%
Pertuzumab	104	0.96%	0.08%	1.02%
Doxorubicin	90	0.00%	-0.37%	1.54%
Avelumab	86	0.00%	-0.20%	1.08%
Ifosfamide	64	0.00%	-0.01%	1.22%
TOTAL	3308	0.57%	-0.01%	2.11%

ABOUT THE PORTFOLIO

inclusiv is a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to support your needs for sterile compounding from the design and building of your sterile compounding environment, to the preparation and verification of your products, through the ongoing management and optimization of your pharmacy operation.

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GNL-KOC-2500011