# Analytical control by DRUGLOG® UV spectrophotometry: how relevant is it for internal ranges?

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## Context

- DRUGLOG®: automated identification and dosing system using UV-visible spectrophotometry

→ Quality control of 40% of the 11,000 chemotherapy bags prepared per year at the UPC

- Analyses based on calibration ranges provided by the manufacturer (database shared between centers)
- Restarting the control following an interruption → Several concentration non-conformities detected

**Error related to a DRUGLOG® range issue ?**

## Objective

Comparison of the performance of locally prepared calibration curves with those of the manufacturer in order to use the most suitable curves for each molecule and to secure the control process.

## Materials and methods

1. *Selection of the four most commonly prescribed cytotoxic molecules: 5-fluorouracil, irinotecan, paclitaxel, oxaliplatin*

*Preparation for each molecule of a calibration range and control points (CP)*
*Repeatability tests over 3 days/molecule*

2. *Analysis of preparations of oxaliplatin (17), 5FU (16), paclitaxel (14), and irinotecan (10) on both DRUGLOG® ranges*

*Manufacturer ranges*

*Locally prepared ranges*

*Comparison of theoretical concentrations and results obtained between the two ranges at DRUGLOG®*

## Results

| Molécules | n | DRUGLOG® range | | Local range | |
|---|---|---|---|---|---|
| | | Qualitative NC | Quantitative NC | Qualitative NC | Quantitative NC |
| Oxaliplatin | 17 | 0 | 0 | 3 | 0 |
| 5FU | 16 | 0 | 3 | 1 | 1 |
| Paclitaxel | 14 | 0 | 0 | 0 | 0 |
| Irinotecan | 10 | 0 | 0 | 7 | 0 |

*Table 1. Details of non-conformities (NC) observed: quantitative or qualitative for each molecule based on bag preparations. n=number of bag preparations*

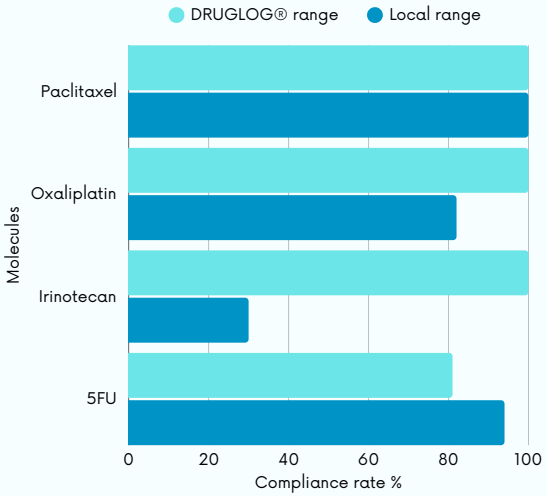


*Table 2. Comparative analysis of the results of pocket concentrations obtained between the DRUGLOG® range and local ranges, n = 57 pocket preparations and error threshold = 15%.*

- The local range appears to be more effective for 5FU analysis
- Both ranges are equivalent for paclitaxel control; for oxaliplatin, the manufacturer's range has a 100% compliance rate
- A significant variation is observed for irinotecan, with better control by the manufacturer's range

## Conclusion/Discussion

- The results show variability in performance depending on the molecules and ranges used
- Local ranges for 5FU, paclitaxel, and oxaliplatin could be used routinely, but more data is needed for irinotecan
- Greater collaboration with the manufacturer is needed to adapt or optimize the calibration ranges in order to qualify the automated system with the aim of ensuring reliable, reproducible, and secure quality control in routine use