

Naveau M¹, Annereau M², Fleury T², Sakji I¹, Villain A¹, Marliot G¹, Feutry F¹.

¹Oscar Lambret Center, Pharmacy, Lille, France; ²Gustave Roussy Institut, Pharmacy, Villejuif, France

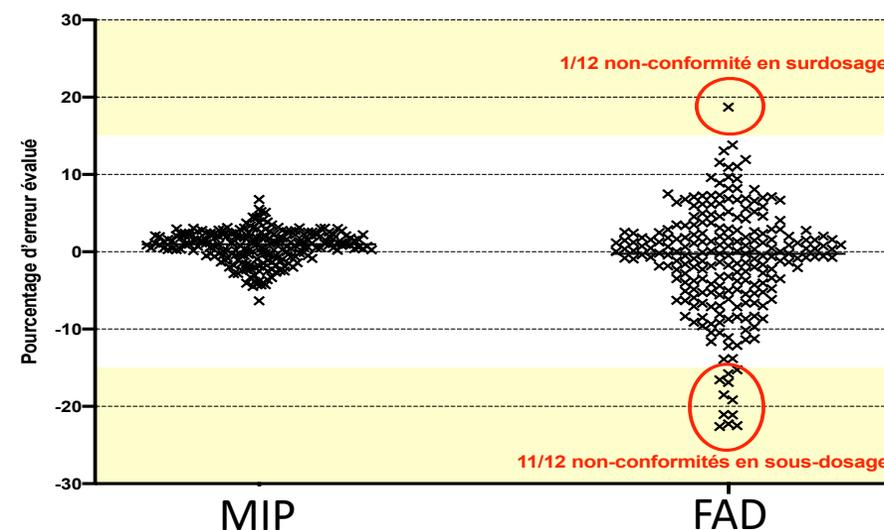
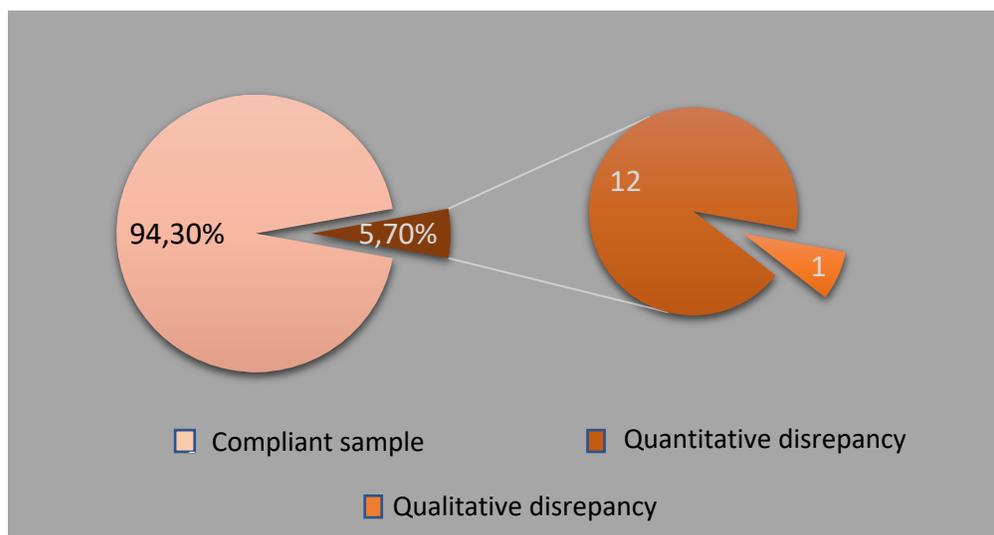
Introduction

To ensure security and quality of chemotherapy masterful preparations, an in-process securing with gravimetric control and identification of each bottle by DataMatrix code was implemented and allows 100% control of our production (Diffusers and clinical trials included). Even if we demonstrated the accuracy of the weighing, the step of identification of each bottle done before the preparation doesn't leave out that the sample was in a wrong bottle. A consistency control between our **in-process monitoring** (MIP) and the **final analytical dosage** (FAD) by **QCprep** was considerate.

Material and method

228 preparations, accepted by our MIP control and representative of our production were sampled and dosed helped by a QCprep. The analytical compliance was set to +/- 15% of errors of the dose. In case of discrepancy MIP/FAD, the non-compliances (NC) were analyzed on a case-by-case basis.

Results



Hypothèses émises :

- **Issue of homogenization** : in agreement with the high under-dosage proportion (11/12) and feedbacks of centers managing the analytical control
- **Difficulties to dose the cisplatin (4/12)** : the cisplatin that absorbs a little and on a specific way in the UV-Visible
- **Low volume (<3mL) (3/12)** : gravimetric control difficult or high impact of dilution?
- **Drugs to reconstitute (3/12)** : quality of initial dissolution and cumulative gravimetric steps

Conclusion

The 228 preparations dosages confirmed the security of our preparations process, especially on a qualitative point of view (only one NC because of an analytic control error). The quantitative discrepancies are explained because of analytic difficulties (homogenization of preparations, non-specific spectral analysis, results impacted by high dilutions) and not because of gravimetric difficulties, even if the case of drugs to reconstitute can insert cumulative weighing errors. These results, completed by universality (diffusers and EC), low cost, low technical level and the possible intervention during preparations management validates our choice of parametric liberation for chemotherapies masterful preparations