

THE VALIDATION OF CONTROL METHOD : THE GRAVIMETRIC ANALYSIS IN CYTOTOXIC DRUG PREPARATION



L01 – Cytostatics
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BACKGROUND

Our production unit realizes **35 000 cytotoxic drug preparations per year** in isolator chamber (IC). The control method is done by in process **gravimetric analysis coupled with scan identification**, led by software with interactive instructions. The balances are certified once a year, yet outside the IC.

PURPOSE We need to validate the control method with the two components: the weighing scales and the software

MATERIEL AND METHODS



- A** Qualification with standard weights inside and outside the IC
Tests performed: **fidelity, accuracy and eccentricity**
- B** Evaluation of the balance bias
A **comparison to visual control** was performed : 6 syringes with different volume were made and verified by a third person, 15 times weighed to obtain the total error.

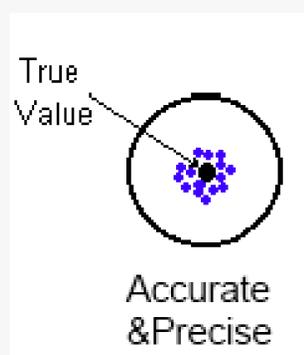


- C** Software analysis : Specificity (SP) and Sensitivity (SE)
SP : Software extraction to study **false positives** which are the forced steps (false positives) over 6 months
The steps refused by the software but accepted by the pharmacist because of the correct volume read are called "forced steps"
- D** SE : Fake cytotoxic preparations with deliberately wrong volume to determine the rate of the **false negatives**

RESULTS

- A** **Metrological tests** enable to qualify the balances

Difference is non significant between inside and outside the IC



- B** 6 syringes weighed 15 times each
90 weighings



The **bias** of the weighing scales fluctuates between 0.94 and 4.40%

50ml syringe is responsible for the biggest values of the bias

Difference is non significant between inside and outside the IC

- C** 15 227 preparations realized
189 334 steps of fabrication → **2023 forced steps (4,1%)**

Major forced steps :

1. Weighing of **syringe with cytotoxic (41%)**
50ml syringe responsible of 41% of this forced stage.
In 85% of cases, it's due to the volume to collect which has a decimal value
2. Weighing of **final pouch (23%)**.
In 98% of cases, fabrication was beforehand forced with the **"syringe with cytotoxic step"**

- D** 6 syringes with "error volume" weighed 30 times each
180 weighings
142 detected errors (**79%**)

Non detected errors are at 80% due to the **1ml syringe**

If 1ml syringe excluded : 95% of the errors are detected

CONCLUSION

The gravimetric analysis is the control method in **92% of our preparations**. It is **rapid, accurate and sensitive**. In real conditions, cytotoxics with small final volume are controlled visually. This method doesn't permit to control volume inferior to 1ml. A work is in the progress in order to **improve the specificity and minimize the forced steps**.