

# Long-term stability of 5-Fluorouracil at standardized rounded doses in sodium chloride infusion polyolefin bags, stored at room temperature

PP-013

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## Introduction

Five-Fluorouracil (5-FU) is one chemotherapeutic agent commonly used by oncologists as the standard therapy of advanced colorectal cancer. The Centralized Intra-Veinous Admixture Service (CIVAS) of the hospital has started to produce 5-FU at standardized rounded doses (SRD) in 2015 to implement dose-banding.

## Aim of the study

The aim of this study is to prove the long-term stability of 5-FU at selected standardized rounded doses.

## Materials and Method

- Ten polyolefin bags, five containing 700 mg and five 800 mg of 5-FU in sodium chloride solution (614 mg/100 ml and 689.7 mg/100ml respectively) were prepared under aseptic conditions and stored at room temperature for 24 days.
- At days 0, 2, 4, 7, 9, 11, 15, 17, 22 and 24, two aliquots were withdrawn from each solution.
- The first one was frozen for HPLC (Alliance, model 2695, Waters Association, Milford Massachusetts) analyses and the second one went through physical stability tests including PH (inoLab, WTW GmbH, Weilheim, Germany), spectrophotometric measurements (Genesys 10 UV, Spectronic Unicam) at 350, 410, 550 nm to avoid turbidity, visual and microscopic inspection at 10 fold magnification after centrifugation.
- All aliquots were defrost at the same time to proceed to HPLC analyses to reduce technical variability.

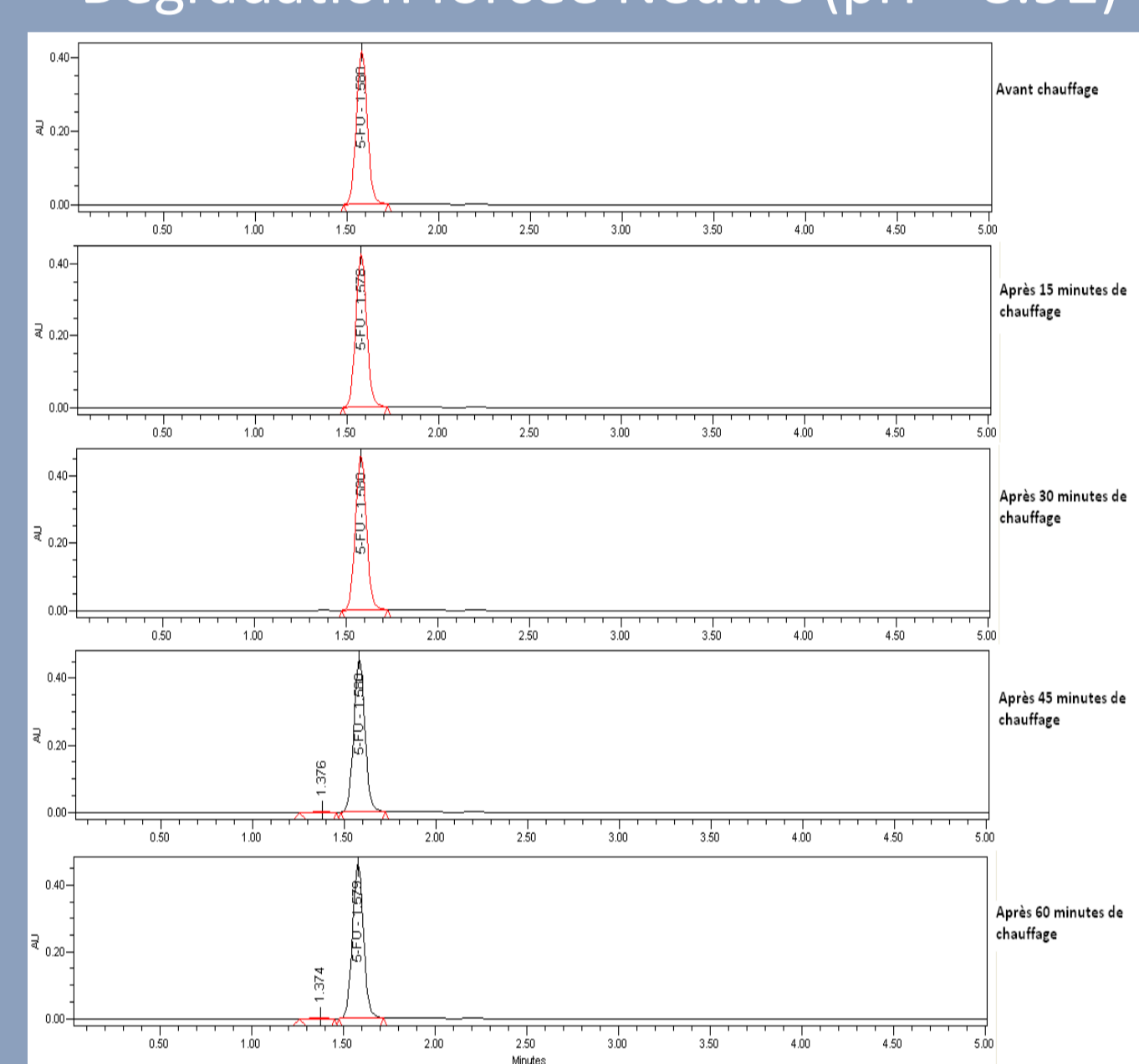
## References :

- Soumoy L, Pirlot C, Decoster C, Gillet P, Hecq JD. Etude préliminaire pour l'implémentation d'un dose-banding de chimiothérapie anticancéreuse. Journal de Pharmacie de Belgique 2015 ; 97(3) :24-35  
- Hecq JD, Godet M, Jamart J, Bihin B, Galanti L. Etude systématique de la stabilité chimique à long terme de solutions de médicaments injectables prêts à l'emploi produites par une Unité Centrale de Reconstitution d'Injectables. Journal de Pharmacie de Belgique 2015 ;97 (3) :36-44

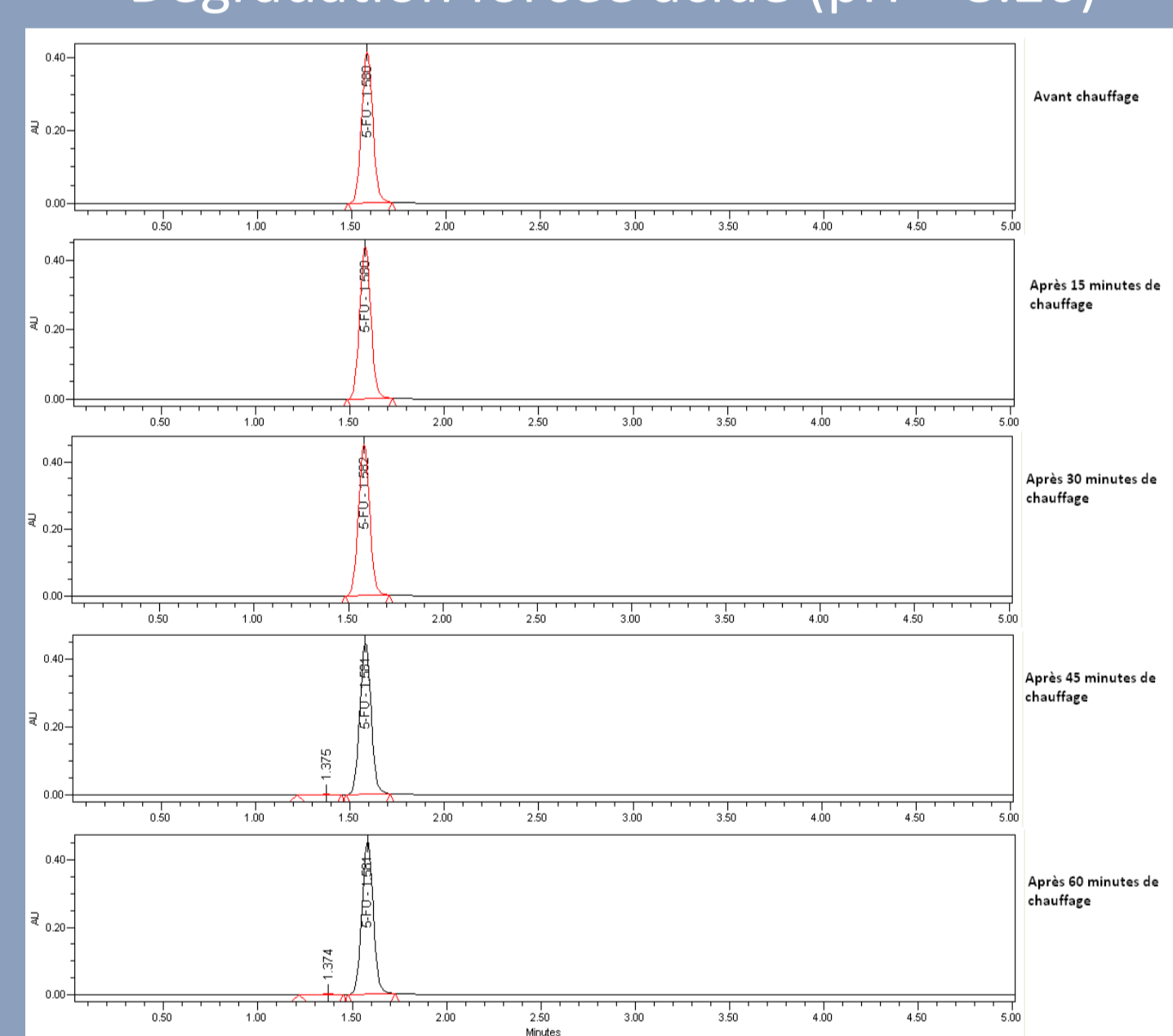
## Results

- The concentration of the solution can be considered stable for at least 24 days because the lower limit of the 95 per cent unilateral confidence interval on the mean remains greater than 90 per cent of the theoretical concentration.
- There were no color change, opacity or turbidity observed in the solutions over the time.
- The microscopic observation didn't show any crystal. The pH remains stable during the study and there were no change in absorbance.

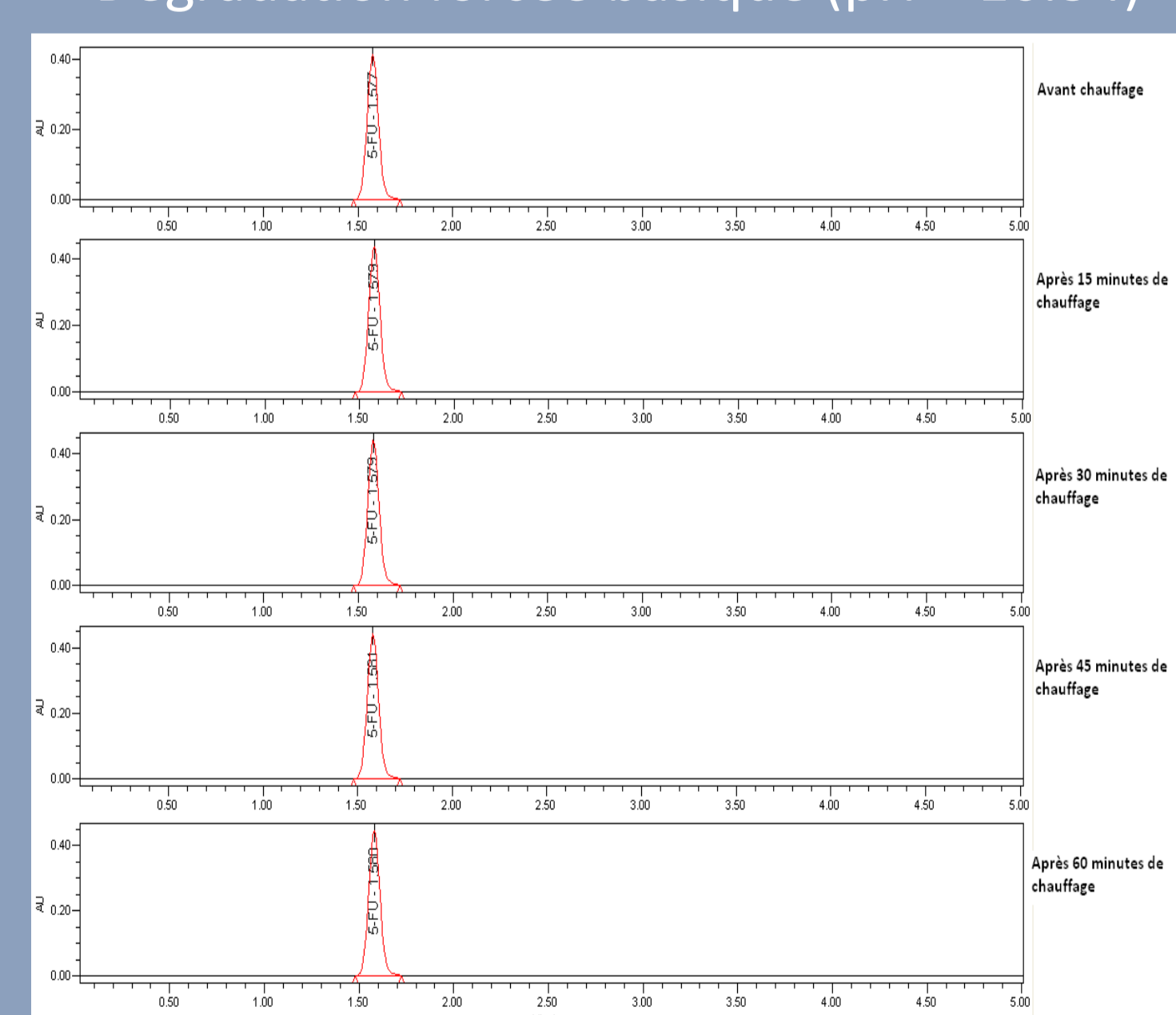
### Dégradation forcée Neutre (pH = 8.92)



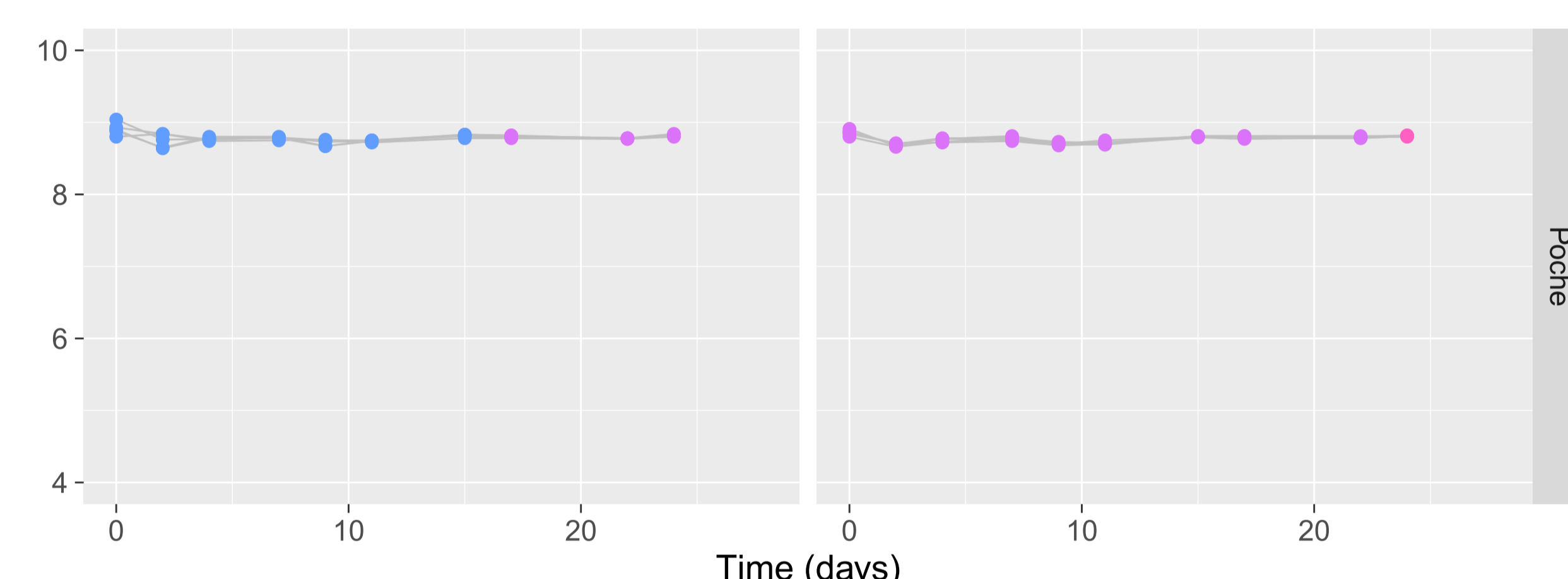
### Dégradation forcée acide (pH = 8.26)



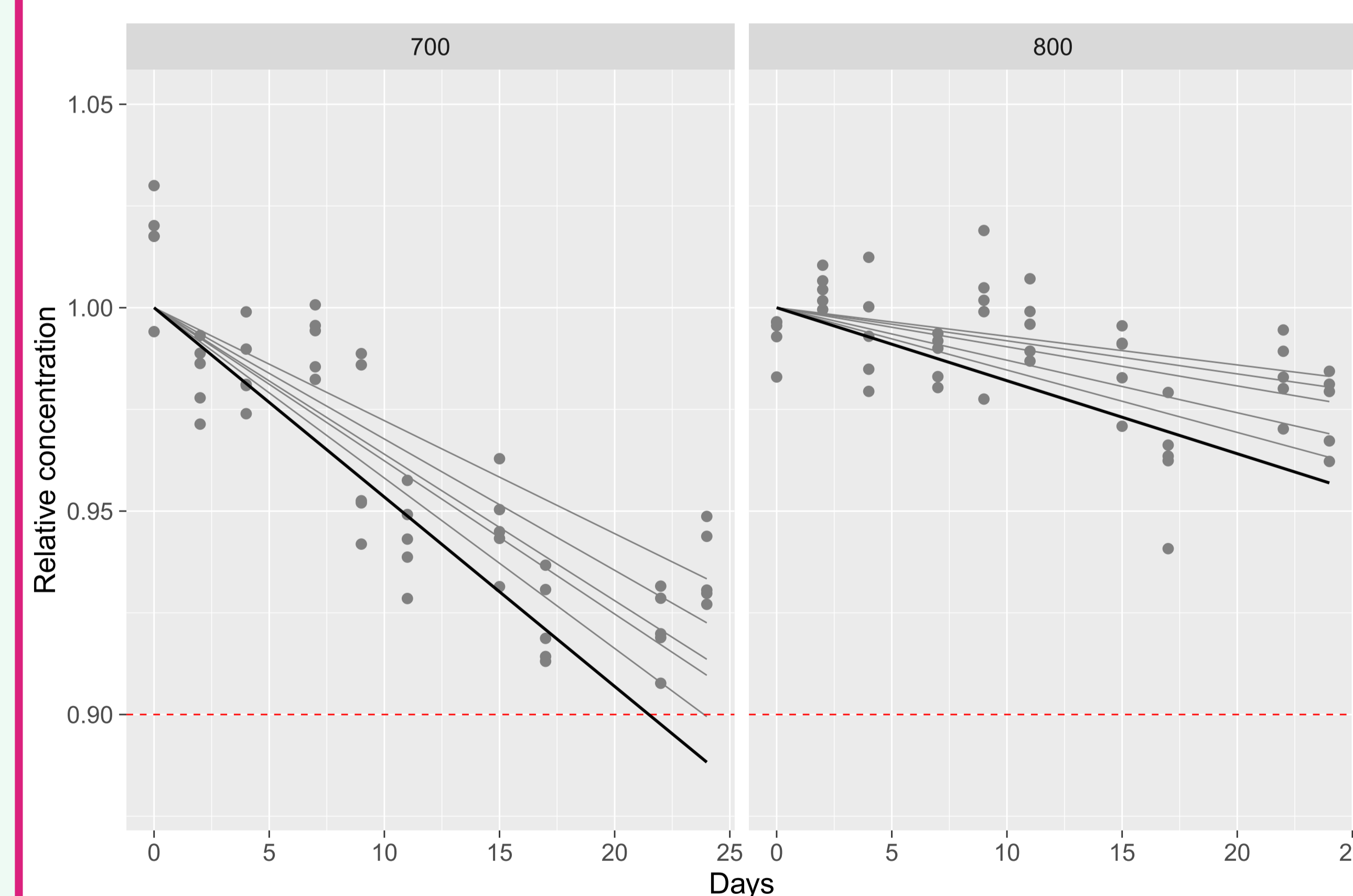
### Dégradation forcée basique (pH = 10.34)



### Evolution of pH in 700mg and 800mg bags



### Evolution of concentration in 700mg and 800mg bags



## Conclusion

Within the limits of this study, 5-FU can be considered stable for 24 days at room temperature in polyolefin bags and at selected SRD of 700 mg and 800 mg/ bag. These results allow us to use it in this way for dose-banding.