Long-term stability of 5-Fluorouracile at standardized rounded doses (SRD) in two types of portable infusion devices

PP-018

J.-D. Hecq[1,4],M. Closset[2], S. Onorati[2], B.Bihin[3,4], C. Decoster[1], P Gillet[1], F. Gillard[1], A. Tondu[1], L.Galanti[1,4]
[1]Department of Pharmacy, [2]Medical Laboratory, [3]Scientific Support Unit, [4]Drug stability Research Group
CHU UCL Namur, site Godinne | Avenue G. Therasse 1, 5530 Yvoir

Introduction

The Centralized Intra-Venous Admixture Service (CIVAS) of the hospital has started to implement dose-banding for 5-Fluorouracile (5-FU), one chemotherapeutic agent commonly used for colorectal cancer. The dose-banding of this molecule includes polyolefin bags and portable infusion devices at standardized rounded doses (SRD).
The portable infusion devices are of two types: Folfuser® SV 2.5 ml/h Baxter® and Myfuser® XM 2.5 ml/h Canox®

Aim of the study

The aim of our study is to prove the long-term stability of 5-FU in portable infusion devices at selected SRD and to compare the two kinds of devices.

Materials and Method

- Twenty infusion devices containing 5-FU in sodium chloride solution were prepared under aseptic conditions and stored at room temperature for 27 days: 5 Folfusor® 4000 and 5000 mg and 5 Myfuser® 4000 and 5000 mg.
- At days 0, 2, 4, 7, 9, 11, 15, 17, 22, 24, 28 at room temperature and days 0, 1, 2 at body surface temperature, two aliquots were withdrawn from each solution.
- The first one was frozen for HPLC (Alliance, Waters Association) analyses and the second one went through physical stability tests including PH , spectrophotometric measurements at 350, 410, 550 nm, visual and microscopic inspection after centrifugation.
- All aliquots were defrost at the same time to proceed to HPLC analyses to reduce technical variability.

References :
Galanti L & al. Can J Hosp Pharm 2009 ; 62 (1) : 34-38

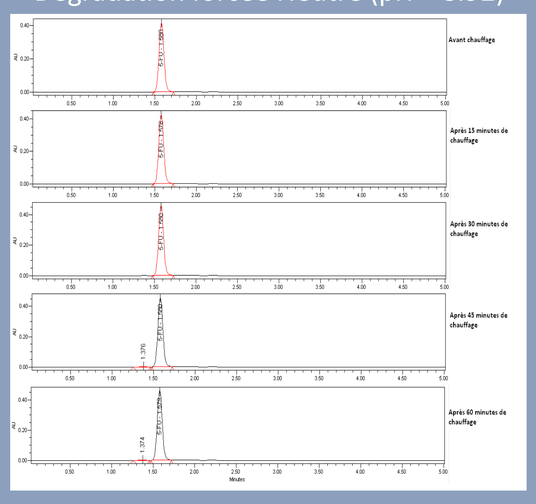
Possible conflict of interest : nothing to disclose.

22-24 March 2017

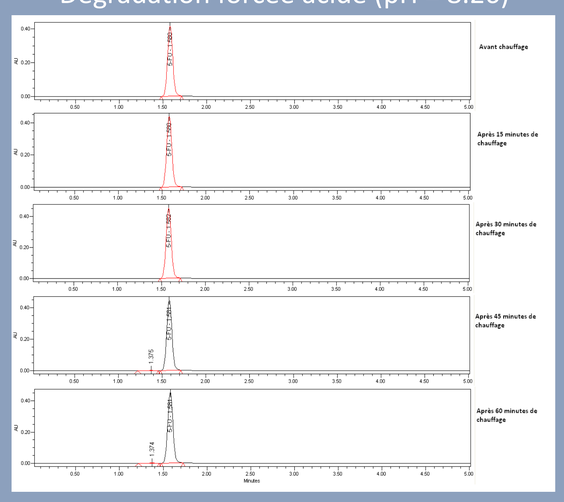
Results

- The concentration of the solution can be considered stable for at least 28 days in MyFuser® and 27 days in Folfusor® 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 was no color change, opacity or turbidity observed in the solutions.
- The pH measurements remain stable over the time and there were no change of absorbance.
- The microscopic observations didn't show any crystal.

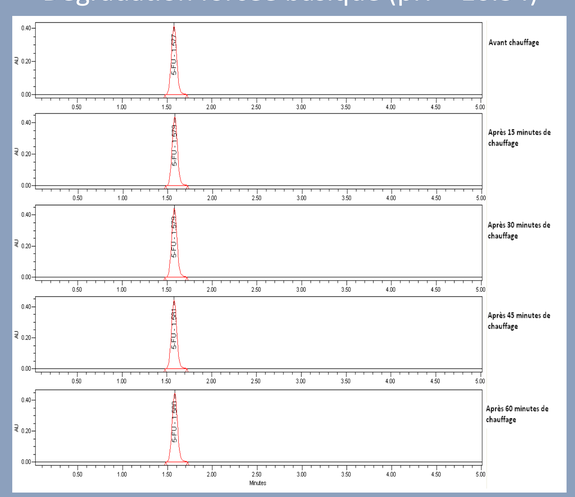
Dégradation forcée Neutre (pH = 8.92)



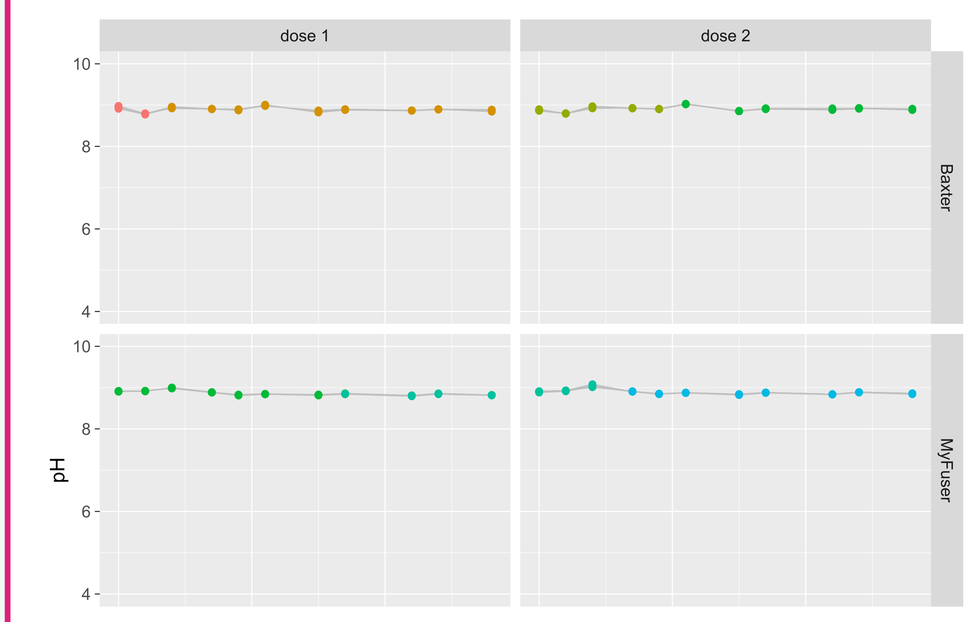
Dégradation forcée acide (pH = 8.26)



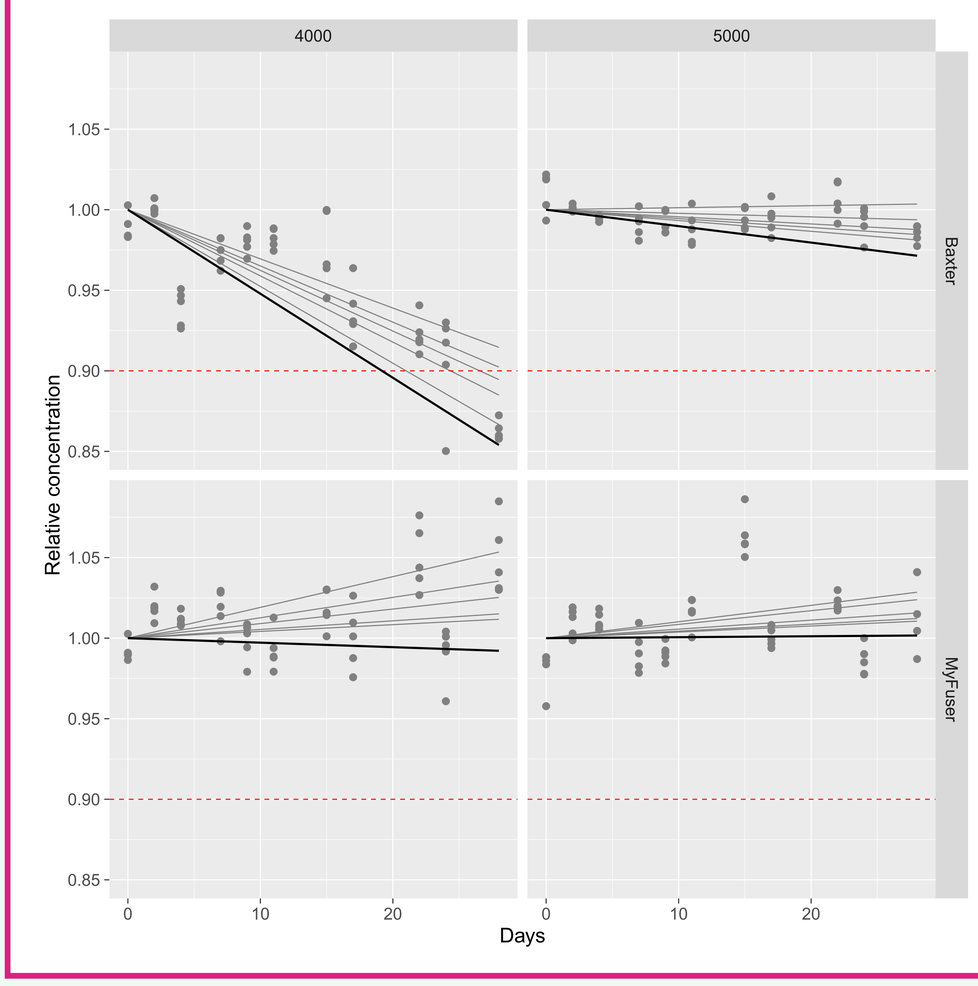
Dégradation forcée basique (pH = 10.34)



Evolution of pH in 4000mg and 5000mg devices



Evolution of concentration in 4000mg and 5000mg devices



Conclusion

Within the limits of our study, 5-FU can be considered stable for at 27 days in Folfusor® and at least for 28 days in Myfuser®. These results allow us to use portable infusion devices at selected SRD for ambulatory chemotherapy of 5-FU.