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


1Department of Pharmacy, 2Medical Laboratory, 3Scientific Support Unit, 4Drug 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: Fofusor® SV 2.5 ml/h Baxter® and Myfusor® 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 Fofusor® 4000 and 5000 mg and 5 Myfusor® 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2, 4, 7, 9, 11, 15, 17, 22, 24, 28 at room temperature and days 0, 1, 2 at body surface temperature, two aliquots were withdrawn from each solution.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:

Results
- The concentration of the solution can be considered stable for at least 28 days in Myfusor® and 27 days in Fofusor® because the lower limit of the 95th percentile unilateral confidence interval on the mean remains greater than 90% 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.

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