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The anticancer preparation unit of our university hospital produces hospital preparation batches (PH) of 2-day diffusers of 5-fluorouracil (5FU) at 4 g, 4.5 g and 5 g using a pump distribution. Their expiration date is set at 14 days after a study in 2015 of flow conservation on Homepump<sup>®</sup> diffusers. A market change was made in favor of Folfusor SV 2ml/h Baxter<sup>®</sup> diffusers in which physicochemical stability was demonstrated by the laboratory over a period of 42 days (D).

The objective is to **evaluate the conservation of the flow rate of Folfusor SV 2ml/h diffusers over a storage period of 28 J in order to extend the expiration of our PH.**

## MATERIEL ET METHODE

- Standard ISO 28620:2020 : **SV2** flow accuracy of +/-15% i.e [1.7 -2.3 ml/h]
  - **Average flow test on n = 30 diffusers**  
**Semi-automated filling with 103 ml of 0.9% NaCl**  
Unclamping at D0, D14, D15, D16, D17, D21, D22, D23, D24 and D28
  - **Average flow test on n = 3 diffuseurs**  
**from our PH batches (Two 5FU 5 g diffusers and one 4 g diffuser)**  
→ Unclamping at D26, D28 et D42
- Storage at room temperature until unclamping
- After unclamping, connected to an infusion bag and placed in the oven at 36.7°C
- Weighing at H0 H3 H7 H24 H32 H48 H50 H53

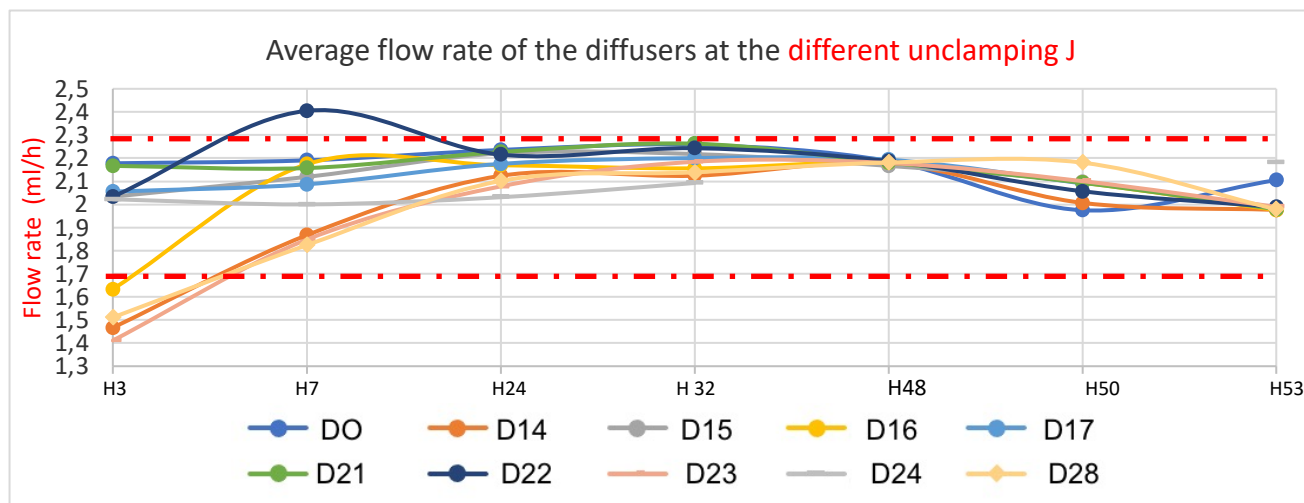
$$\text{Flow rate} = \frac{\text{Infusion bag weight ou } \Delta \text{ diffusers}}{\text{elapsed time}}$$



## RESULTATS

**For n=30 SV2: all of the NaCl was diffused at H48, average flow rate = 2.08 +/- 0.07 ml/h**

For n=5 diffusers: significant occasional variations in flow rate with a return to the norm at the other analysis times.



For n = 3 5FU diffusers

- **Average flow rate over 48 hours on D26 and D28 respectively of 2.05 +/- 0.07 ml/h and 2.0 +/- 0.08 ml/h, which is within the norms.**
- On D42 the broadcasters didn't broadcast.

## CONCLUSION

**Conservation of an average flow rate at H48** compliant up to 28 days after their preparation. Flow rate variations (<10%) may be due to NaCl according to Baxter<sup>®</sup> data.

→ Extension of the **unclamping deadline to 28 days for an expiry of 30 days.**