

WICH ORGANISATION TO OPTIMIZE VIDAZA® PRODUCTION?

INTRODUCTION

According to the SPC, VIDAZA® is stable 8h between 2 °C and 8 °C if reconstituted with sterile water for injection (SWI) at ambient temperature, and 22h if reconstituted with cold SWI (2-8°C). Stability studies have been demonstrated a stability up to 5 days after reconstitution with cold SWI.

In 2018, our Cytotoxic Production Unit (CPU) produced 1,407 VIDAZA® preparations. 36 (2.56%) of these preparations were not administered and destroyed due to the 8h stability. The cost loss is estimated at 22,000€.

OBJECTIVES

The objective of this study was to optimize the reconstitution of VIDAZA®, in particular with cold SWI in order to increase its stability.

MÉTHODS

A brainstorming was held with the member of the unit.

For each proposition, temperature readings of the SWI were made using a thermometer to measure time elapsed between the exit of cold storage room and a temperature above 8 °C.



Solutions proposed :

To use 50mL glass SWI bottles stored in a Cold Storage Room (CSR)



To use 500mL SWI Ecoflacs® stored in a CSR



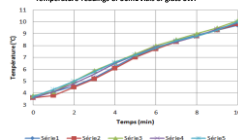
To use 4mL SWI syringes previously filled in an isolator and stored in a CSR



To use frozen 20mL SWI pods

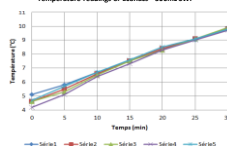
RESULTS

Temperature readings of 50mL vials of glass SWI



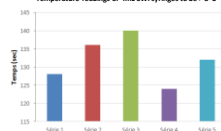
The temperature of the 50mL vials of glass SWI was higher than 8 °C in on average 6.50min

Temperature readings of Ecoflacs® 500mL SWI



The temperature of Ecoflacs® 500mL SWI was higher than 8 °C in on average 17,20min

Temperature readings of 4mL SWI syringes to be > 8 °C



the temperature of the 4mL SWI syringes previously filled was higher than 8 °C in on average 2min20.

CONCLUSION

The proposal to use 20mL frozen SWI pods was rejected because of the necessity a needle for the sampling. The use of 4mL syringes of SWI previously filled in isolator and stored in CR in a sterile box has been adopted. This organization allows to save time during the preparation of VIDAZA® and avoids a significant cost loss.