

Context/Objective

number of chemotherapy preparations

Acquisition in 2021 of a robot for the preparation of cytotoxic agents and monoclonal antibodies. (RIVA™, ARxIUM)



MINIFULL SET® (MF) continuous 5-FU administration devices cannot be robotized



MINIFULL SET®
(Micrel Medical)

The aim is to determine the best MF preparation process in terms of work ergonomics, precision and control of chemical and microbiological risks.

Methods : For all processes, a closed system Chemolock® (ICU Medical) is used.

	Process 1 (P1)	Process 2 (P2)	Process 3 (P3)	Process 4 (P4)
Stock Solution preparation (c =40mg/ml)	RIVA™	RIVA™	Pump MediMix Vigo®	/
MF filling (4400mg of 5FU)	Pump Baxa Repeater®	Pump MediMix Vigo®	Pump MediMix Vigo®	Pump MediMix Vigo®
	Flow rate of 165mL/min	Flow rate of 135mL/min		Flow rate of 114mL/min



Pump Baxa Repeater®



Pump MediMix Vigo®

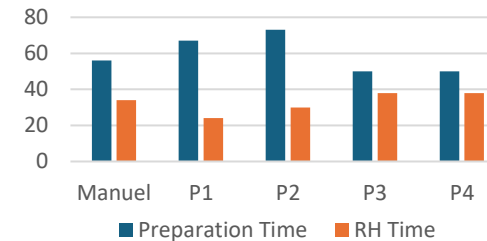
Several criteria are evaluated per process :

- Preparation time : grid to record preparation time
- Precision : gravimetric control of MF
- Chemical risk : samples of pump, work space, du 1st MF et du 5th MF at the septum of the Chemolock® using a swab and 0.1mL of Sterile Water For injection
- Microbiological risk : Media Fill Test (MFT) with Tryptone Soy Broth (TSB), TSB MFs were filtered, inoculated onto 4 culture media



Results :

Preparation Time



Gravimetry

✓ All MF are conforms

	MediMix Vigo®	Baxa Repeater®
% error	0,09	3,94
Standard deviation	0,00	0,45

Chemical tests

Detection of 5-FU on the samples.

	Work space	Pump	1 st MF	5 th MF
P1	No	No	Traces	Yes
P2	No	No	Traces	Yes
P3	No	No	Yes	Yes
P4	No	No	No	No

Media Fill Test

✓ No microbiological growth was found for each process.

Discussion/Conclusion :

The MediMix Vigo® pump with an integrated scale shows better precision results. TRA results indicate effective control of microbiological risk regardless of the filling location (PSM adjacent to the RIVA or isolator). Preparation according to P3 and P4 procedures is faster; however, P1 and P2 could reduce the preparator's mobilization time by 26%. Chemical contamination is observed, except for P4. The chemical contamination appears to be due to the pump flow rate being too high relative to the capacity of the closed system used. Additional tests will be conducted to study the impact of the flow rate on the Chemolock® and chemical contamination.

Process	Precision	Preparation time	RH Time	MFT	Chemical contamination
1	X	X	✓	✓	X
2	✓	X	✓	✓	X
3	✓	✓	X	✓	X
4	✓	✓	X	✓	✓