

SUMMARY

In order to:

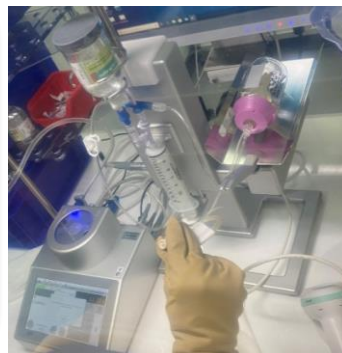
- To reduce the risk of musculoskeletal disorders (MSDs)
- Secure the preparation process
- Optimize production

→ Acquisition of a Medimix Vigo® & +One® automated compounding system for the preparation of 5-Fluorouracil (5-FU) infusion pumps, consisting of:

- A peristaltic pump connected to the diluent (D5W)
- A syringe pump connected to the 5-FU
- An integrated balance



Objective : Performance Qualification of the automated system



MATERIALS & METHODS

❖ Qualification of the **peristaltic pump**

- ❖ Gravimetric measurement (independent qualified balance)
- ❖ D5W
- ❖ 6 volumes tested : 5, 10, 20, 50, 150, 240 mL
- ❖ Repeated filling operations performed three times a day over three days

❖ Qualification of the **syringe pump**

- ❖ Gravimetric measurement
- ❖ 5-FU simulated using 0.9% NaCl solution (for all tests)
- ❖ 6 volumes tested : 5, 10, 20, 50, 100, 240 mL
- ❖ Repeated filling operations performed three times a day over three days

❖ Compliance of the **priming procedure** (peristaltic pump and syringe pump)

- ❖ Determination of the required volumes
- ❖ Gravimetric measurement (volume compliance)
- ❖ Post-priming colorimetric assessment (priming sequence: D5W → "5-FU" → D5W) / Use of a colored NaCl solution bag

❖ Qualification of the **dual-channel filling process**

- ❖ Gravimetric measurement
- ❖ D5W + NaCl
 - ❖ 4 concentrations tested : 1, 10, 35, 45 mg/mL
 - ❖ During three days
- ❖ Post-priming colorimetric assessment (priming sequence: D5W → "5-FU" → D5W)

Assessment of

- **Precision (repeatability/reproducibility)**
- **Trueness**

Acceptance criteria: < 2% for coefficients of variation (CVs) and trueness deviations

❖ Metrological qualification of the **integrated balance**

- ❖ Use of certified reference weights
- ❖ Precision / Trueness / Eccentricity measurements

❖ Performance of a **Media Fill Test (MFT)**

RESULTS

Peristaltic pump



- Precision: CV < 2% for repeatability and reproducibility
- Trueness:
 - Volumes > 20 mL: All deviations < 2%
 - 10 mL: 13/18 deviations > 2%
 - 5 mL: No deviation < 2%



Syringe pump



- Precision: CV < 2% for repeatability and reproducibility
- All trueness deviations < 2%



Priming

- Required volume of D5W: 30 mL (→ 40 mL in practice)
- Required volume of 5-FU: 5 mL (→ 10 mL in practice)
- No visible coloration after D5W priming



Dual-channel filling process

- Precision: CV < 2% for repeatability and reproducibility
- All trueness deviations < 2%
- No visible coloration after D5W injection



Integrated balance



- Precision: CV < 2% for repeatability and reproducibility
- All trueness deviations < 2%
- Eccentricity OK



MFT

- No microbial growth on Days 1, 2, 7, and 14



DISCUSSION / CONCLUSION

→ Automated system qualified only for solvent volumes > 20 mL



Filling with the peristaltic pump based on gravimetric measurement:

- Pump draws the solvent until the balance reaches the target weight
- Few milliseconds delay
- Injected volume too high

Integrated balance not designed as an independent external control, but as part of the filling process → Inaccuracy for low volumes

→ Filling using the syringe pump (+One® module) is not linked to the balance, allowing qualification of all volumes delivered using the syringe pump (5-FU)

→ **The two-line automated system can be used for filling 5-FU infusion devices, but is unsuitable for low volumes**, raising concerns regarding the future preparation outside the elastomeric infusion pump context