


Evaluation of the performance of an automated system for the preparation of cytotoxic bags

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Background:

The increased use of chemotherapy drugs leads hospitals to rationalize their production. Automated systems are one of the possible solutions.

Purpose:

Evaluate the PharmaHelp® (Fresenius) automated system comparing different working conditions (Accuracy (trueness and repeatability) and productivity).

Materials and methods

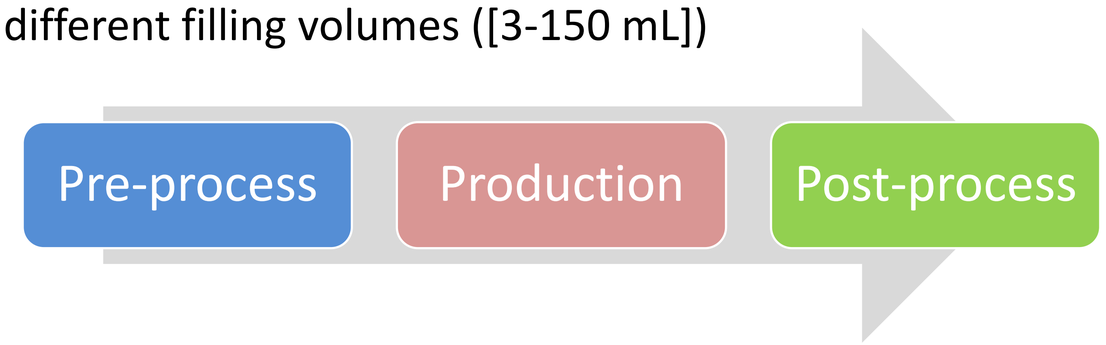
Accuracy study:

- Gravimetric and chemical analyses (Phenylephrine as tracer)
- 10 different volumes of IV bags'filling [0.5-250 mL] tested
- 4 studied working conditions:
  - filling position,
  - size of syringes (20/60mL),
  - day of manufacture,
  - manufacturing methods: dose banding/individualized doses,
- Result discussed with limits ±3%, ±5%, ±10% (IC95)

Productivity study:

Production time is estimated for each manufacturing's step

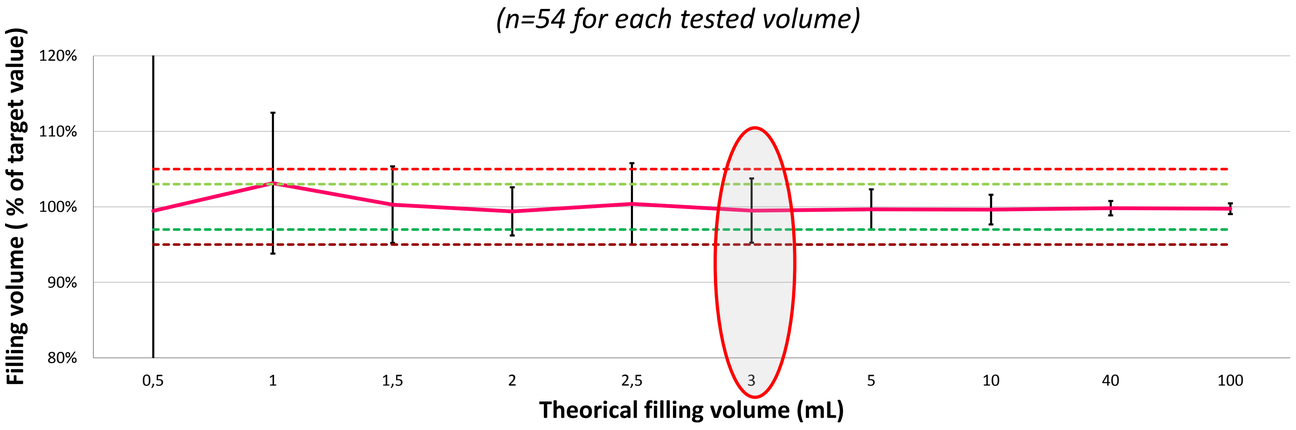
Test was performed by 10 IV bags production run with different filling volumes ([3-150 mL])



Results/Discussion

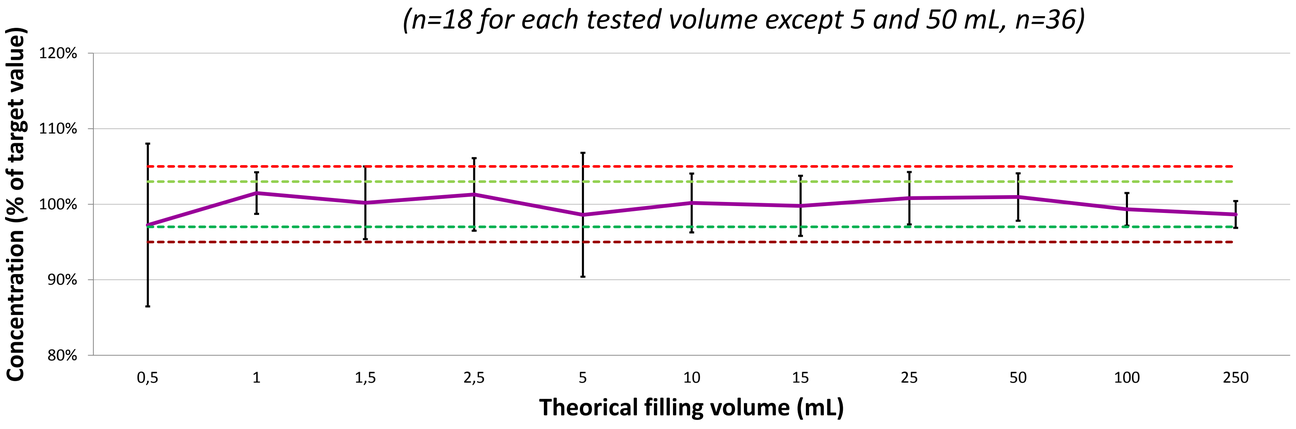
Gravimetric study of filling accuracy

(n=54 for each tested volume)



Analytical study of filling accuracy

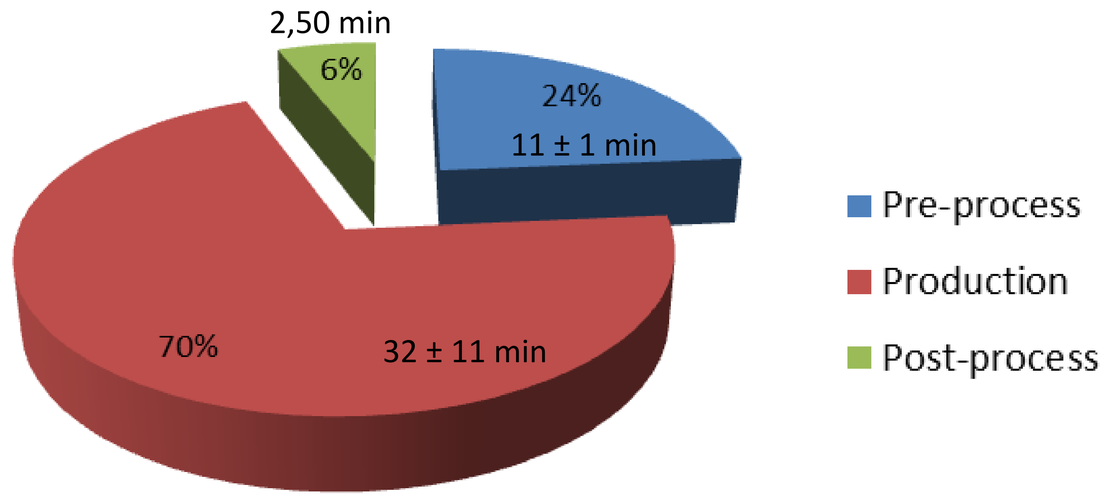
(n=18 for each tested volume except 5 and 50 mL, n=36)



- True filling [0.5-250 mL] (97-103%)
- Accuracy from a filling volume of 1 mL (±10%), 3 mL (±5%), 100 mL (±3%)
- Same accuracy for the 2 manufacturing methods and the 2 sizes of syringes (Student test, p>0.05, n=360 (individualized doses), n=180 (dose-banding), Student test, p>0.5, n=270 for each syringes)
- Repeatability: performance independent of the filling position (Student test, p=0.36, n=180) and the working day (Student test, p>0.05, n=540).

Productivity study: Average duration of each manufacturing's step

(n=11; Average duration of each manufacturing: 45 ± 12 min)



- Production time depends on the injected volume and the size of the syringe
- Production lasts 45±12 minutes for 10 bags:
  - 30% for manual steps (pre-processing: 24%, post-processing: 6%)
  - 70% for automated step

Conclusion:

- Production of IV bags from liquid active components
- Accurate filling from a volume of 3 mL for <±5% and 1 mL for <±10% limits
- Potential of such automated systems : increase productivity and guarantee the safety of patients and operators

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eahp european association of hospital pharmacists

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The study was performed on a PharmaHelp® system freely loaned by Fresenius
http://pharmacie.hug-ge.ch/rd/posters.html