Pharmacie des Hôpitaux universitaires de Genève

Preparation of capsules for individual patients: validation of the operator's accuracy

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Introduction

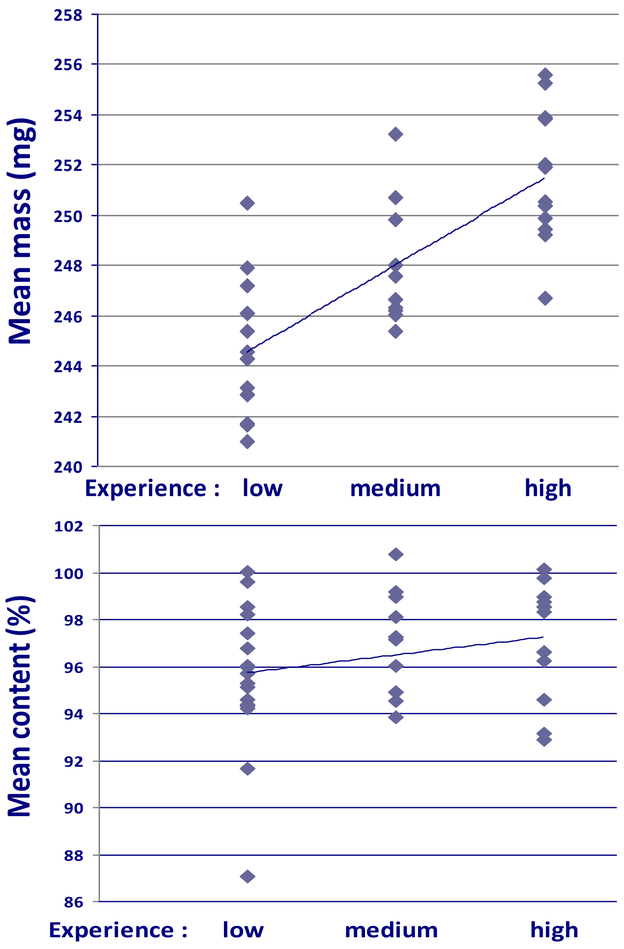
Preparation of capsules is common in hospital pharmacy when an adapted dose is not available on the market. According to the Good Manufacturing Practices, validation of processes and operators are essential to ensure the quality of preparations. Our purpose was to evaluate and validate the operator's accuracy during the manual process of capsules preparation.

Material & Methods

- Each operator : Manual preparation, 3 batches of 100 capsules
  Each capsule (size 2, 250 mg) 6 mg of phenylephrine as tracer
- Sampling of 10 capsules in critical points of the capsule filler (2 in every corner and 2 in the center) for uniformity of mass and content (Ph. Eur.)
- Phenylephrine assay : validated Capillary Electrophoresis-UV method.
- Results analysis considering : operator's experience → low, medium and high (years of experience and the frequency of execution).

Results

42 Batches **14** Operators (11 technicians and 3 pharmacists).



- ✓ **Mass uniformity**: All batches **CONFORM** (Phar. Eur.)
- ✓ **Content uniformity**: **6** batches (14%) **Not CONFORM**.
  - 9/14 (64%) passed the test for 3/3 batches,
  - 4/14 (29%) for 2/3
  - 1/14 (7%) for 1/3.
- ✓ **Operators**
  - low experience (n=6),
  - medium experience (n=4),
  - high experience (n=4)),

Mean mass (±SD)	Mean content (±SD)
244.6 (±2.4)	95.6 (±3.0)
247.9 (±2.3)	96.9 (±2.1)
251.6 (±2.7)	97.0 (±2.5)

Conclusion

All operators displayed adequate skills to uniformly fill capsules, with a trend to a better performance by experienced operators.

However, insufficient homogenization of the mixture was observed, independently of the experience.
Further studies are needed to evaluate different systems from producing consistent mixtures.

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