

Background

Automation is being used more frequently in the manufacturing site of hospital pharmacies. With the PharmaPrinter® (CurifyLabs, Helsinki, Finland), it is also possible to produce suppositories. Ideally the machine facilitates production and ensures reproducibly high quality of the suppositories.

Objectives

Suppositories (n=10) were made both manually (SuH) and by a machine (SuP). Processes and results were compared. We focused on appearance, mass and content of the suppositories, as well as preparation time.

Materials and methods

Suppositories were prepared with 5 mg diclofenac-sodium each (total mass: 1 g). SuppoBase® by Curify Labs (containing hard fat, polysorbate 80 and colloidal silica) was chosen for the PharmaPrinter® (SuP), hard fat was chosen for the handmade suppositories (SuH).

The final suppositories were assessed in terms of appearance, mass uniformity and content uniformity (Ph.Eur. 2.9.40). Diclofenac-sodium content was assessed by a validated HPLC-UV method, adapted from Ph.Eur, after methanolic extraction. Additionally, production time was reported.

Results

All results are shown in table 2. The SuH had a smooth surface and finish. SuP had a smooth surface as well, but a hole on the finish and the moulds were not filled completely (see Fig. 3). The total masses are higher for the SuH, because in this process the moulds are filled by volume. For the SuP the moulds were filled by mass up to 1 g. Both kind of suppositories met the criteria for mass uniformity and content uniformity according to Ph.Eur. 2.9.40.

The preparation times were 65 min. (SuH) resp. 48 min. (SuP).

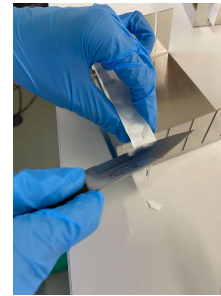


Fig. 1: manual production



Fig. 2: machine production

	Modified Method
Column	Kinetex® C18 (core-shell), 150 x 4.6 mm, 5 µm
Mobile phase (isocratic)	34 T phosphate buffer pH 2,5 66 T methanol
flowrate	1.2 ml/min
Oven temperature	25°C
Injected volume	10 µl
Wave length (UV detection)	254 nm
Chromatographic time	7 min.
Retention time Diclo-Na	Ca. 4.5 min.

Table 1: HPLC Method



Fig. 3: Hole in the Suppos. of SuP

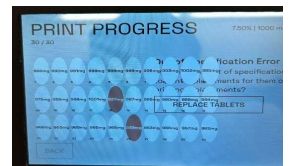


Fig. 4: SuP – Printer Screen with mass deviation > 10% (red)

	Manually - SuH	Machine - SuP
Surface	smooth	smooth
Finish	smooth	hole
Moulds filled	completely	Not completely
Mass (mean ± RSD)	1.09 g ± 0.56%	0.97g ± 1.06%
Content (mean ± RSD)	4.91mg ± 0.84%	4.68 ± 1.30%
Preparation time	65 min.	48 min.

Table 2: Results investigation suppositories

Conclusion

Both techniques resulted in suppositories of good quality, whereas production time for machine production was a bit shorter. Explanatory videos from the homepage of CurifyLabs also make it easier for inexperienced manufacturers. During the process the PharmaPrinter® documented each mass of the resulting suppository. If there are deviations of 10%, the suppository was marked and can be sorted out. The PharmaPrinter® can therefore facilitate and automate the production of suppositories.