

Background

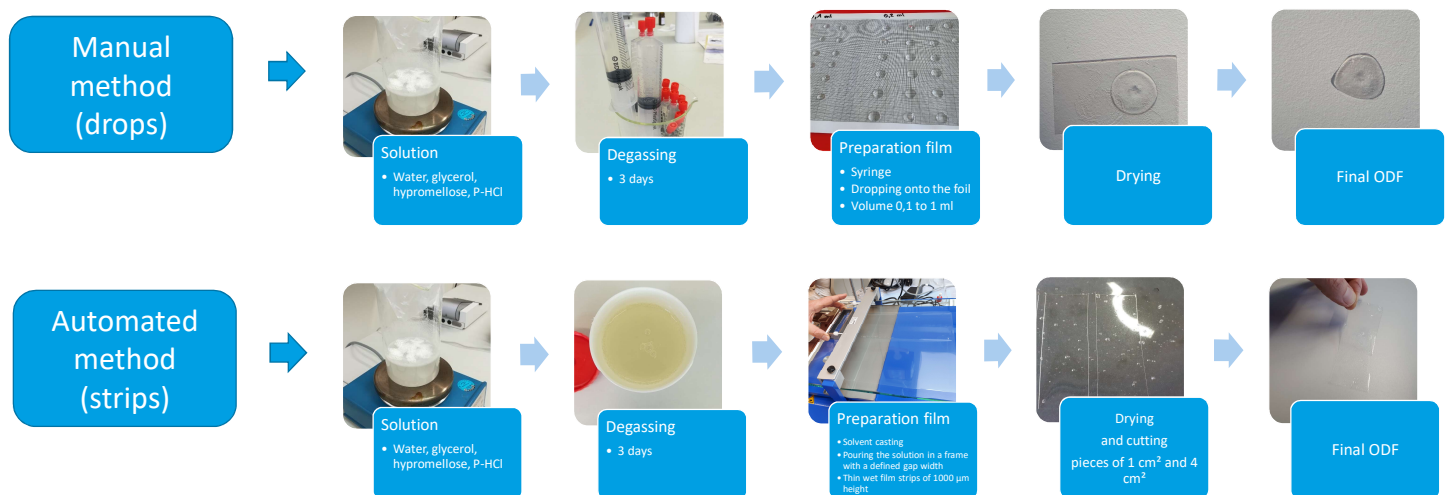
Fast dissolving orodispersible films (ODF) provide an alternative formulation for patients with swallowing difficulties. Preparing this films is not yet part of the curriculum in pharmacy school and therefore it has to be learned for yourself.

Objectives

ODF were produced using different techniques, both a manual and an automated method. After preparation we wanted to clarify, if it was possible to prepare some films with these methods. If it's possible to incorporate an active ingredient. And what characteristics the films have.

Materials and methods

Different solutions were created. All of them contained hydroxypropylcellulose, glycerol, water and – for quantitative analysis – Propranolol hydrochloride (P-HCl). The films were manufactured using two different methods, both a manual and an automated method.



All ODF were dried for three days by room temperature and analysed for

- 1) Their thickness with a micrometer screw (Erichsen Model 497, s. picture 1)
- 2) Dissolving rates. Therefore the ODFs were exposed every 30 seconds to a drop of purified water. Time till the film become permeable was measured (s. picture 2)
- 3) The content of P-HCl via UV/Vis spectroscopy.



Picture 1: thickness



Picture 2: dissolution time

Results

Results are shown in the table on the right.

All the films from the manual method were consistently thicker than those from the automated method. The films from the manual method also had longer dissolution times. All films dissolves within 4 minutes, regardless of the production method.

The content of Propranolol Hydrochloride was 0,34 mg per cm² for the automated method. The required dose of P-HCl can be adjusted by the size of the film piece. For a dose of 5mg a film of approx. 15 cm² is required.

The drops lead to a fixed dose and could be adjusted by the volume. The measured amount of active ingredient was close to expected target values with the larger drops being within 98% of target.

Conclusion

Both methods led to suitable films. All films showed short dissolution rates and even active ingredients had been inserted during manufacturing process. The automated method led to thinner films and therefore to less active ingredient per cm². To receive a dosis of 5mg P-HCl about 15 cm² has to be taken orally. Nevertheless the manual method is an easy method to implement without specialized equipment.

	Film 1 cm ² (automated)	Film 4 cm ² (automated)	Film 0,1ml (manual)	Film 0,2ml (manual)	Film 0,5ml (manual)	Film 1ml (manual)
Preparation	automated	automated	manual	manual	manual	manual
Thickness n=3	50 µm ± 2 µm	50 µm ± 2 µm	135 µm ± 5 µm	154 µm ± 3 µm	172 µm ± 6 µm	178 µm ± 4 µm
Size	Square Edge length 1 cm	Square Edge length 2 cm	Diameter 1 cm	Diameter 1,2 cm	Diameter 1,6 cm	Diameter 2,1 cm
Dissolution time n=3	2,08 min ± 0,53 min	2,41 min ± 0,31 min	Too small	Too small	3,6 min ± 0,03 min	3,6 min ± 0,23 min
Content Propranolol hydrochloride (P-HCl) n=3	0,34 mg ± 0,003 mg	1,38 mg ± 0,028 mg	0,47 mg ± 0,012 mg	0,92 mg ± 0,016 mg	2,46 mg ± 0,001 mg	4,90 mg ± 0,167 mg
% from the expected content of P-HCl	-	-	94 %	92 %	98 %	98 %
When a dose of 5mg P-HCl should be administered	14,7 cm ²	14,5 cm ²	10,6 Drops	5,4 Drops	2 Drops	1 Drop