Background and importance Fast dissolving orodispersible films (ODF) provide an alternative formulation for patients with swallowing difficulties. Preparing these films is not yet part of the training in pharmacy school and is learned by self-training.

Aim and objectives ODFs were produced using a manual and a technical technique. These were then analysed.

Material and methods All solutions contained hydroxypropylmethylcellulose, glycerol 85%, water and, for quantitative analysis, propranolol hydrochloride (P-HCl). The films were manufactured using two different techniques: (1) dropping the solution with a syringe onto a foil: volume 0.1–1 mL; (2) solvent casting: pouring solution into a frame of 1000 μm height; fabricating stripes with the help of a film layering machine (Erichsen, Germany); after drying film stripes were cut in 1 cm² and 4 cm² pieces.

All ODFs were dried for 3 days at room temperature and analysed for:

1. height with a micrometer screw (Erichsen, model 497)
2. dissolving rates. The ODFs were exposed every 30 s to a drop of purified water put onto the film. Time was measured to when the film became permeable.
3. their content of P–HCl via UV/Vis.

Results Film strips were 50 μm in height. The smallest drops of 0.1 mL had 135 μm height; those of 1 mL had a gauge of 175 μm. Dissolving rates depended on the thickness and gauge of the film. Time ranged from 2 to 3.6 min. 98% of the expected amount of P-HCl content was in the 1 mL drops, with only 90% in the smaller 0.1 mL drops. The content of active ingredients was 0.34 mg P-HCl in the film pieces of 1 cm². It raised linearly to 1.38 mg P-HCl in 4 cm² pieces.

Conclusion and relevance Both methods led to suitable films. All films showed short dissolution rates and active ingredients had been inserted during the manufacturing process. The solvent casting method led to flatter films and therefore less active ingredient per cm². To receive a dose of 5 mg P-HCl, about 15 cm² of film should be taken orally. Further investigations are needed to improve this. Nevertheless, the dropping method is an elegant and easy method.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest
Background and importance Ceftolozane/tazobactam is a combination of a new third generation cephalosporin and a β-lactamase inhibitor used to treat infections caused by multidrug resistant Pseudomonas aeruginosa. The usual dose is 3 g/day. To the best of our knowledge, no stability data for ceftolozane/tazobactam at 62.5 mg/mL in polypropylene syringes (PS) for intensive care units or at 25.0/12.5 mg/mL in elastomeric devices (ED) for home administration have been published.

Aim and objectives The objective was to study the stability of ceftolozane/tazobactam solutions at 62.5/31.25 mg/mL, diluted in 0.9% sodium chloride (0.9% NaCl) or dextrose 5% in water (D5W), in PS after storage at 20 °C, not protected from light, and solutions at 25.0/12.5 mg/mL diluted in 0.9% NaCl or D5W in ED after storage at 37 °C, during a 48 hour period.

Material and methods Three preparations for each condition were prepared. At the time of analysis, one sample for each preparation was analysed by a validated high performance liquid chromatography method coupled to a photodiode array detector at 220 nm. Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm, as recommended by the European Consensus Conference), pH values were measured.

Results Linearity was validated with an R² of 0.9999. The coefficients of variation on repeatability and intermediate precision were <2%. In 0.9% NaCl and D5W, ceftolozane/tazobactam retained more than 90% of the initial concentration after 48 hours in PS. After 24 hours in ED, the concentration of ceftolozane remaining was 91% in 0.9% NaCl and 89% in D5W. A major degradation product, observed during the forced degradation, appeared progressively after 8 hours. At 24 hours in ED, it represented 3.8% of the total peak area. A second degradation product eluted with tazobactam. After 24 hours, the solutions yellowed in the ED. During the stability study, pH values were all between 5.95 and 5.26.

Conclusion and relevance In ED, ceftolozane/tazobactam was unstable at 37 °C in D5W and in 0.9% NaCl. Cef tolozane/tazobactam was stable at 62.5/31.25 mg/mL in PS diluted in 0.9% NaCl or D5W for 48 hours, allowing continuous intravenous infusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Background and importance Vancomycin is a time dependent antibiotic of the glycopeptide family. The recommended dose of vancomycin is 30–40 mg/kg/day. For an adult, the maximum daily dose can reach 4 g. In clinical practice, vancomycin is mostly administered by continuous infusion. After hospitalisation, administration of concentrated solutions in elastomeric devices would allow a home care service and a better quality of life for the patient.

Aim and objectives The objective of this work was to study the stability of vancomycin solutions at 37.5 mg/mL (4.5 g in 120 mL of solvent) diluted in 0.9% sodium chloride (0.9% NaCl) or in dextrose 5% in water (D5W), in elastomeric devices, protected from light, at 37 °C for 48 hours.

Material and methods Chemical stability was analysed by high performance liquid chromatography coupled to a photodiode array detector and by pH measurements after preparation, after 24 hours and 48 hours of storage. The method was validated according to the International Conference on Harmonisation Q2 (R1). Three elastomeric devices for each condition were prepared. Physical stability was evaluated by a visual and subvisual inspection at each time of analysis (turbidimetry by UV spectrophotometry at three wavelengths: 350, 410 and 550 nm).

Results For each solvent, solutions at 37.5 mg/mL retained more than 90% of the initial concentration for 48 hours: for 0.9% NaCl (minimum 96.49%±1.12%; maximum 100.94%±0.51%) and for D5W (minimum 102.75%±1.19%; maximum 104.67%±1.15%). During the study, pH values did not decrease after 48 hours in the two solvents. During the subvisual examination, there was no significant difference between the different analysis times regardless of the solvent used. No colour change was reported during the study.

Conclusion and relevance Vancomycin solutions at 37.5 mg/mL in 0.9% NaCl and D5W were stable in elastomeric devices for 48 hours at 37 °C, protected from light. Home administration for this concentration is possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Background and importance Cloxacillin is an antibiotic indicated in methicillin sensitive Staphylococcus aureus infections. The usual curative dosage ranges from 8 to 12 g/day, divided into 4–6 daily administrations. Continuous infusions are frequently used in the intensive care unit. The administration of concentrated solutions in an electric syringe pump would reduce the water supply and the number of daily intakes.

Aim and objectives The objective was to study the stability of cloxacillin solutions at 125 mg/mL diluted in 0.9% sodium chloride (0.9% NaCl) and in dextrose 5% in water (D5W), stored in polypropylene syringes, unprotected from light, at 20–25 °C for 48 hours.

Material and methods Chemical stability was analysed by high performance liquid chromatography coupled to a photodiode array detector and by pH determination after preparation, and after storage for 6, 24 and 48 hours. The analytical method