

## Section 3: Production and compounding

3PC-055 ABSTRACT WITHDRAWN

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3PC-057 USING DIFFERENT TECHNIQUES TO PREPARE ORODISPERSIBLE FILMS IN A HOSPITAL PHARMACY

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**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 hydroxypropyl-methylcellulose, 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 cm<sup>2</sup> and 4 cm<sup>2</sup> 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 cm<sup>2</sup>. It raised linearly to 1.38 mg P-HCl in 4 cm<sup>2</sup> 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 cm<sup>2</sup>. To receive a dose of 5 mg P-HCl, about 15 cm<sup>2</sup> 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

3PC-058 PHYSICO-CHEMICAL STABILITY OF MEROPENEM IN POLYPROPYLENE SYRINGES AT 41.7 MG/ML FOR INTENSIVE CARE UNITS

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**Background and importance** Meropenem is a broad spectrum antibiotic used to treat severe infectious. The maximum dose recommended is 6 g/day. A stability not exceeding 24 hours has been demonstrated by many research teams in different publications. Only two studies were performed at 40 mg/mL in polypropylene syringes with conflicting stability results: 4 hours and 8 hours. Meropenem is a time dependent antibiotic; its continuous administration improves its efficiency.

**Aim and objectives** The objective of this work was to study the stability of meropenem solutions at 41.7 mg/mL (2 g in 48 mL), diluted in 0.9% sodium chloride (0.9% NaCl) or dextrose 5% (D5W), in polypropylene syringes not protected from light, after preparation and after 4 and 8 hours at 20–25°C.

**Material and methods** Three syringes for each condition were prepared. At the time of analysis, one sample from each preparation was analysed by high performance liquid chromatography coupled to a photodiode array detector at 297 nm. The method was validated according to the ICH Q2 (R1). 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** The method was validated with an r<sup>2</sup> of 0.9999. The coefficients of variation on repeatability and intermediate precision were <2%. In 0.9% NaCl, meropenem at 41.7 mg/mL retained more than 90% of the initial concentration after 8 hours. In D5W, after 8 hours of storage, only 86.1%±0.1% of the initial concentration remained and a major colour change was also observed (yellowing). In the D5W, we detected a significant increase in absorbance at 450 and 550 nm in 8 hours. During the stability study, pH values were all between 7.55 and 7.79.

**Conclusion and relevance** In D5W, meropenem was unstable, with chemical and physical instability. Meropenem was stable at 41.7 mg/mL in polypropylene syringes diluted in NaCl 0.9% for 8 hours. This new stability data allows continuous administration.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-059 PHYSICO-CHEMICAL STABILITY OF CEFTOLOZANE/TAZOBACTAM IN POLYPROPYLENE SYRINGES AT 61.5/31.25 MG/ML AND IN ELASTOMERIC DEVICES AT 25.0/12.5 MG/ML

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