Abstracts

Section 3: Production and compounding

3PC-055  
ABSTRACT WITHDRAWN

3PC-056  
ABSTRACT WITHDRAWN

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 hydroxypropylmethylcellulose, glycerol 85%, water and, for quantitative analysis, propanolol 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 mm height; those of 1 mL had a gauge of 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.

Conflict of interest No conflict of interest

REFERENCES AND/OR ACKNOWLEDGEMENTS


Conflict of interest No conflict of interest

3PC-058  
PHYSICOCHEMICAL 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 r² 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


Conflict of interest No conflict of interest

3PC-059  
PHYSICOCHEMICAL 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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Background and importance Ceftriaxone and aztreonam are extensively used in France. Clinical data are needed for their stability in different devices in the pharmacy. The objective of this study was to compare the physical and chemical stability of ceftolozane/tazobactam in polypropylene syringes and elastomeric devices using different methods.

Aim and objectives The aim was to test the 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.

Material and methods Ceftolozane/tazobactam was prepared in polypropylene syringes and elastomeric devices at 61.5/31.25 mg/mL and at 25.0/12.5 mg/mL. The physical and chemical 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 r² 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


Conflict of interest No conflict of interest
Background and importance Cefotolozane/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 cefotolozane/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 cefotolozane/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 20–25°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, cefotolozane/tazobactam retained more than 90% of the initial concentration after 48 hours in PS. After 24 hours in ED, the concentration of cefotolozane 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, cefotolozane/tazobactam was unstable at 37°C in D5W and in 0.9% NaCl. Cefotolozane/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

3PC-061 PHYSICOCHEMICAL STABILITY OF CLOXACILLIN SOLUTION IN POLYPROPYLENE SYRINGES AT 125 MG/ML IN 0.9% SODIUM CHLORIDE AND DEXTROSE 5% IN WATER

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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