Stability of 1.0, 0.2 and 0.025 mg/mL Milrinone Solutions Stored in Syringes at 4°C and at Room Temperature (25°C).

Inpatient hospital pharmacies must compound intravenous products and assign an appropriate beyond-use-date (BUD) as per NAPRA standards, when products are not commercially available. Having infusions available as ready-to-administer (RTA) products on nursing units is important for safe and timely administration of medication.

Stability of 1.0, 0.2 and 0.025 mg/mL Milrinone Solutions Stored in Syringes at 4°C and at Room Temperature (25°C).

In this study the concentration was observed to change by no more than 4% during the 90 day study period and the BUD, calculated with 95% confidence, exceeded 155 days for storage of all concentrations, temperatures and diluents.

When establishing a BUD in your institution, the sterile compounding environment and sterility testing of the final product must be considered.

OBJECTIVES

The objective of this study was to evaluate the chemical stability of milrinone prepared in syringes at concentrations of 1 mg/mL (undiluted), 0.2 and 0.025 mg/mL (diluted in either 0.45% sodium chloride or 5% dextrose in water (D5W)) at both room temperature and in the refrigerator.

The concentration of milrinone was evaluated during storage using a validated, stability-indicating liquid chromatographic method with UV detection.

RESULTS

Concentration Results

Concentrations of milrinone for each study day are reported in Table 1 and were observed to vary by 4% or less from the initial concentration throughout the 90-day study period.

Multiple linear regression revealed significant differences in percent remaining due to study day (p = 0.008) and temperature (p = 0.0276) but not concentration (p = 0.108) or diluent (p = 0.635). The calculated T-90, with 95% confidence, exceeded 155.61 days for all concentrations, temperatures and diluents.

CONCLUSIONS

We conclude that 1 mg/mL (undiluted), 0.2 and 0.025 mg/mL diluted in either 0.45% sodium chloride or D5W, stored at either room temperature or in the refrigerator in polypropylene BD syringes are physically and chemically stable for 90 days.

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