Long-term stability of ganciclovir in polypropylene containers at room temperature

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Abstract

Purpose: Ganciclovir is increasingly provided by hospital pharmacy production unit in a readyto-use form, in order to improve the safety of healthcare workers and the efficiency of the organisation. The objective of this study was to develop a stability-indicating method to assay ganciclovir and determine the stability of ganciclovir in syringes (5 mg/mL) and infusion bags (0.25 and 5 mg/mL) at two different temperatures.

Methods: Ganciclovir solutions (0.25 mg/mL and 5 mg/mL) in 0.9% sodium chloride were prepared in 50 mL polypropylene syringes or 100 mL polypropylene infusion bags and stored at 2–8°C and 23–27°C. The chemical stability was measured using a stability-indicating Ultra High Performance Liquid Chromatography coupled to mass spectrometry method. Physical stability was assessed by visual inspection.

Results: No significant loss of ganciclovir under any of the tested conditions was observed in this study. All solutions remained clear through the study period.

Conclusion: All tested formulations remained stable for at least 185 days independently of container type, temperature or concentration studied.

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