

Stability of busulfan solutions in polypropylene syringes and infusion bags as determined with an original assay

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Abstract

Purpose: The stability of busulfan solution in 0.9% sodium chloride and stored in polypropylene syringes or infusion bags was evaluated.

Methods: Busulfan solutions (0.54 mg/mL) were prepared and transferred to 50-mL polypropylene syringes and 100- and 500-mL polypropylene infusion bags and stored at 2–8 and 23–27°C. Chemical stability was measured using a stability-indicating, ultrahigh performance liquid chromatography coupled to mass spectrometry method. The stability of busulfan was assessed by measuring the percentage of the initial concentration remaining at the end of each time point of analysis. The initial busulfan concentration was defined as 100%. Stability was defined as retention of at least 90% of the initial busulfan concentration. A visual inspection of the samples for particulate matter, clarity and color without instrumentation of magnification was conducted at each time point of analysis.

Results: The visual inspection demonstrated no influence of the storage container when busulfan infusions diluted in 0.9% sodium chloride injection were stored at 23–27 °C. No color change or precipitate was observed at this temperature; however, a rapid decrease of the busulfan content in all containers stored at room temperature was observed. Busulfan in syringes was chemically stable for 12 hours, while busulfan in infusion bags (100 and 500 mL) was stable only for 3 hours at 23–27 °C.

Conclusion: Busulfan 0.54 mg/mL solution in 0.9% sodium chloride injection was physically and chemically stable for 30 hours when stored in 50-mL polypropylene syringes at 2–8 °C and protected from light.

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