
Abstract:

Purpose: The stability of dexmedetomidine in polyvinyl chloride (PVC) bags containing 0.9% sodium chloride injection was studied.

Methods: Dexmedetomidine solutions (4, 8, 12, and 20 μg/mL; n = 6 for each) were prepared by removing 2, 4, 6, and 10 mL of 0.9% sodium chloride injection, respectively, from 50-mL PVC bags and injecting 2, 4, 6, and 10 mL of dexmedetomidine 100 μg/mL, respectively. To ensure a homogeneous mixture, the contents of each bag was manually mixed initially and before each sample was removed. All compounding was conducted by a single pharmacist using aseptic technique in a horizontal-laminar-airflow hood at 25 °C. Forced-degradation studies were conducted at 70 ± 1 °C. Stability samples were analyzed using high-performance liquid chromatography electrospray ionization–tandem mass spectrometry (LC/MS-MS) and high-performance liquid chromatography–ultraviolet-light (HPLC/UV) absorbance. Forced-degradation samples were monitored using LC/MS-MS, HPLC/UV, and gas chromatography–MS.

Results: Dexmedetomidine solutions were very stable at 23 ± 2 °C at all four concentrations over the 48-hour testing period. As determined via LC/MS-MS and HPLC/UV methods, over
97% of the initial concentration of dexmedetomidine remained after 48 hours. Extensive HPLC/UV active degradation products could be observed in basic conditions; only minor UV active degradation products were observed in acidic, oxidative, and photochemical conditions.

Conclusion: Dexmedetomidine hydrochloride 4, 8, 12, and 20 μg/mL stored in PVC bags at 23 ± 2 °C was stable for 48 hours, despite a slight decrease in solution pH seen with increasing dexmedetomidine concentrations.
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