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Stability of acetylcysteine in an extemporaneously compounded ophthalmic solution

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Abstract

The stability of acetylcysteine in an extemporaneously compounded ophthalmic solution was studied. Acetylcysteine 10% ophthalmic solution containing 0.025% disodium edetate and 0.5% chlorobutanol in an artificial tears base was prepared and stored at 2-8 degrees C in clear, 15-mL, low-density polyethylene dropper bottles. At 0, 7, 14, 21, 28, 35, and 60 days, a 1-mL sample was removed from each bottle and analyzed for acetylcysteine concentration by high-performance liquid chromatography. Another set of 10% acetylcysteine solutions containing 0.025%, 0.050%, 0.075%, or 0.10% disodium edetate were prepared, stored at room temperature (23-25 degrees C), and analyzed at 0, 7, 15, 30, 40, and 50 days. In the solutions containing 0.025% disodium edetate, acetylcysteine was stable for 60 days at 2-8 degrees C but for less than 7 days at 23-25 degrees C. In the solutions containing 0.75% and 0.10% disodium edetate, acetylcysteine was stable for 40 and 50 days, respectively, at 23-25 degrees C. Acetylcysteine in a 10% acetylcysteine ophthalmic solution containing 0.025% disodium edetate and 0.5% chlorobutanol in an artificial tears base was stable for 60 days at 2-8 degrees C.

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