

Results of an evaluation of the stability of methotrexate in 0.9% sodium chloride injection and 5% dextrose injection are presented” Nissen et al (2017).

Abstract:

Purpose: Results of an evaluation of the stability of methotrexate in 0.9% sodium chloride injection and 5% dextrose injection are presented.

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Methods: Methotrexate concentrated solution (100 mg/mL) was diluted to nominal concentrations of 0.2 and 20 mg/mL in infusion bags containing 0.9% sodium chloride injection or 5% dextrose injection. The filled bags were stored for 28 days at 25 °C and 60% relative humidity and protected from light. Samples were withdrawn for analysis on the day of preparation and after 3, 7, 14, 21, and 28 days. The test program included visual inspections, measurements of pH and infusion bag weight loss, and high-performance liquid chromatography assays to determine methotrexate content and characterize degradation products.

Results: At both evaluated concentrations, methotrexate in 0.9% sodium chloride injection was stable for 28 days; only minor (<0.05%) increases in amounts of known and unknown degradation products were detected. In 5% dextrose injection, methotrexate at the higher concentration was stable for 28 days, with minor formation of degradation products; in the 0.2-mg/mL solution, however, methotrexate was stable for only 3 days. At later time points, an unknown impurity present at a concentration higher than 0.1% was observed.

Conclusion: At concentrations of 0.2 and 20 mg/mL, methotrexate in 0.9% sodium chloride injection was found to be stable for 28 days when stored at 25 °C and protected from light. Under the same storage conditions, methotrexate in a 20-mg/mL solution prepared with 5% dextrose injection was stable for 28 days, whereas a 0.2-mg/mL solution in the same diluent was stable for only 3 days.

Reference:



Nissen, K.B., Jorgensen, L.B., Berg, D.L. and Andersen, G. (2017) Stability study of methotrexate in 0.9% sodium chloride injection and 5% dextrose injection with limit tests for impurities. American Journal of Health-System Pharmacy. 74(9), p.e211-e223.

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