The chemical stability and physical compatibility of tacrolimus i.v. infusion solutions prepared in Excel bags and stored at 23 or 4 °C for up to nine days were studied” Myers et al (2016).

Abstract:

Purpose: The chemical stability and physical compatibility of tacrolimus i.v. infusion solutions prepared in Excel bags and stored at 23 or 4 °C for up to nine days were studied.

Methods: Tacrolimus admixtures (2, 4, and 8 μg/mL) were prepared in Excel bags using 0.9% sodium chloride injection and stored at 23 °C without protection from light or at 4 °C in the dark. Test samples were withdrawn from triplicate bag solutions immediately after preparation and at predetermined time intervals (1, 3, 5, 7, and 9 days). Chemical stability was assessed by measuring tacrolimus concentrations using a validated stability-indicating high-performance liquid chromatography assay. The physical stability of the admixtures was assessed by visual examination and by measuring turbidity, particle size, and drug content.

Results: All test solutions stored at 23 or 4 °C had a no greater than 6% loss of the initial tacrolimus concentration throughout the nine-day study period. All test samples of tacrolimus
Stability of tacrolimus injection diluted in 0.9% sodium chloride injection

admixtures, under both storage conditions, were without precipitation and remained clear initially and throughout the nine-day observation period. Changes in turbidities were minor; measured particulates remained few in number in all samples throughout the study.

Conclusion: Extemporaneously prepared infusion solutions of tacrolimus 2, 4, and 8 μg/mL in 0.9% sodium chloride injection in Excel bags were chemically and physically stable for at least nine days when stored at room temperature (23 °C) without protection from light and when stored in a refrigerator (4 °C) in the dark.

Reference:


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