



Stability of Tetracycline Hydrochloride in a Compounded Mixture

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Background

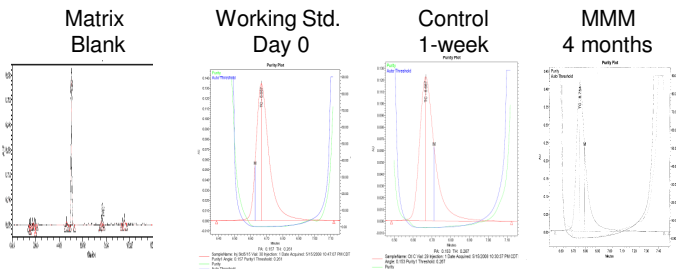
Mary's Magic Mouthwash (MMM) is a mouth rinse compounded in a variety of formulations to treat oral candidiasis which is often a problem for immunocompromised patients. The formulation studied is made from commercial products containing tetracycline HCl (capsules), nystatin (suspension), and diphenhydramine HCl ("DH" elixir). Hydrocortisone is added from tablets or as the powder. Two preparations, varying only in the DH elixir brand used, were evaluated ("OTC" and "Rx"). A survey of 21 pharmacists in Indiana revealed disparity in pharmacist handling of and patient counseling for storage of the mouth rinse.

Objective

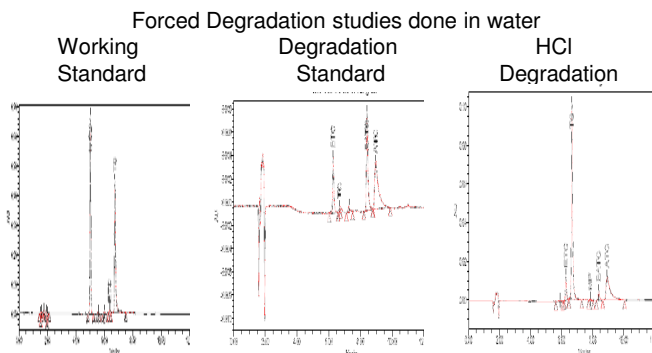
This study was done to generate beyond-use date (BUD) and storage conditions data for mouth rinse suspensions compounded using commercial tetracycline hydrochloride (TC-H) capsules as the drug source.

Methods

A stability-indicating HPLC analysis method was developed to separated tetracycline (TC) from known degradation products (epi-tetracycline (ETC), anhydrotetracycline (ATC) and epianhydrotetracycline (EATC)). Two MMM batches were made, each split into two portions, one stored under refrigeration and one in the dark at room temperature, and assayed weekly.

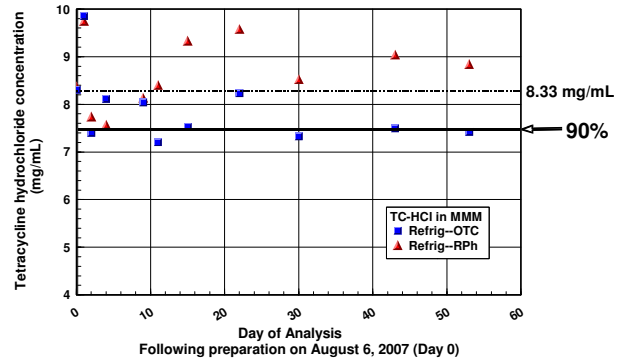


Other

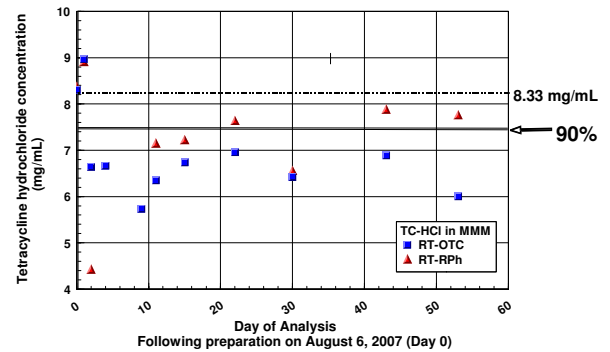


Results

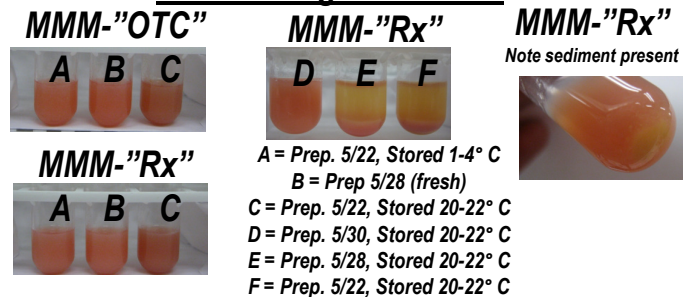
MMM Samples Stored at Under Refrigeration (Refrig, 2 ° C)



MMM Samples Stored at Room Temperature (RT, 21-22 ° C)



Color Change over Time



Conclusions

- Choice of commercial product as ingredient source influences the pharmaceutical elegance (odor, sedimentation and caking).
- Patient must store MMM in refrigerator.
- Patients must be counseled to shake well, and to look for thin sediment if preparation goes unused for more than 2 days.
- TC stability for one preparation tested, refrigerated, supports a BUD of 14 days.
- TC stability exceeds the time that the preparation remains appealing.

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