Stability of extemporaneously compounded mercaptopurine suspensions from commercially available tablets and bulk powder when stored in either plastic or glass containers

Background: Mercaptopurine is commonly used to treat acute lymphoblastic leukemia and it is commercially available only in tablet form. Since tablets may be difficult for children and elderly patients to swallow, many pharmacists compound mercaptopurine suspensions. Stability studies must be conducted in order to assign appropriate beyond-use dates (BUDs) for these suspensions.

Objective: The objective of this study was to evaluate the stability of extemporaneously compounded suspensions from commercially available mercaptopurine tablets and active pharmaceutical ingredient (API) powder when stored in plastic and glass containers at room temperature.

Methods: Mercaptopurine 25 mg/mL suspensions were compounded in a vehicle of Ora-Sweet and Ora-Plus (1:1) using tablets from Gate, Teva, Par, and Roxane, as well as active pharmaceutical ingredient (API). Three suspensions of each type were then stored in amber plastic and glass containers at room temperature. Each mercaptopurine preparation was analyzed using a stability-indicating high performance liquid chromatography method at the following time points: 0, 7, 14, 21, 30, 60, and 90 days. Suspensions were also observed visually and tested for pH at each time point.

Results: The suspensions compounded from Roxane tablets were extremely viscous and were therefore deleted from the study. All other suspensions showed no observed physical changes and maintained greater than 93% of initial concentration of mercaptopurine. There were no statistically significant differences between sources of mercaptopurine or storage containers.

Conclusions: Mercaptopurine suspensions compounded from tablets by Gate, Teva Par, and API in a vehicle of Ora-Sweet and Ora-Plus were stable for 90 days at room temperature. Therefore, a BUD of 90 days is appropriate.