Review of: "The stability of quetiapine oral suspension compounded from commercially available tablets"

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Potential competing interests: The author(s) declared that no potential competing interests exist.

Well-conducted study. Stability information of aqueous quetiapine fumarate suspensions is of practical value to compounding pharmacists. Calculation of the dissolved versus suspended drug enhances the value of this study.

My comments appear below:

1. The statement “Importantly, the stability of these nonaqueous oral QF suspensions was not measured." The USP does not require stability documentation in non-aqueous vehicles because drugs do not degrade in oil suspensions. The USP allows a maximum BUD of 6 months in sweet almond oil at room temperature WITHOUT DOCUMENTATION. These oil suspensions have a pleasant taste, are re-dispersible and are stable for 180 days.
2. Propylene Glycol was used as the levigating agent. Glycerin would have been a better choice because it is sweet and safe for use in pediatric populations.
3. The forced degradation studies show significant degradation in 0.1N HCl within 48 hours. In this context, the 60 day observed stability in acidic vehicles like Ora-Blend is surprising.
4. Paragraph 8 under Results and Discussion states “The targeted concentration in the QF compounded suspensions was 10 µg/mL.” Shouldn't this be 10 mg/mL?
5. The sentence following the one above also needs to specify the units of the measured concentrations, i.e. mg/mL.
6. In the Conclusion, reference is made to “available suspending agents, Ora-Sweet and Ora-Blend”. Ora-Sweet is a sweetening agent, it has no suspending capability. It needs to be combined with Ora-Plus to acquire the ability to suspend insoluble drug powders.