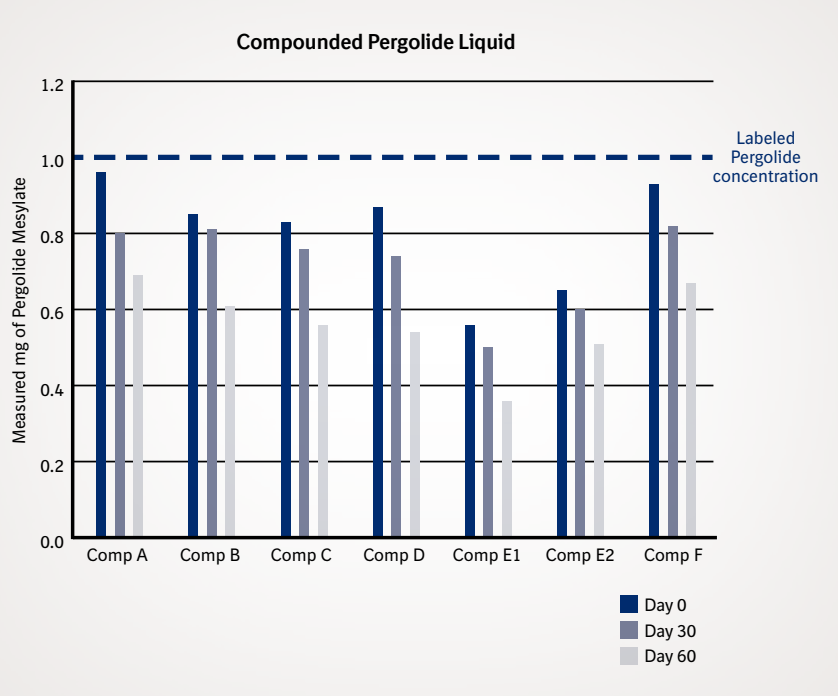
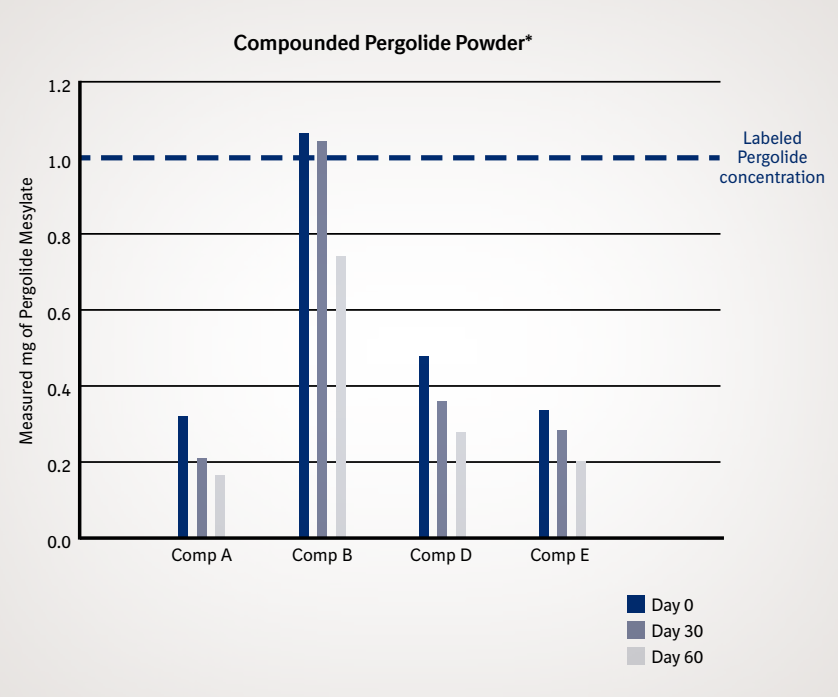
Instability of Compounded Pergolide



The charts to the left are representations of the data reported by Stanley and Knych.[1] Each product was tested for stability on day 0, 30 and 60 at 25°C. All samples claimed a 1 mg pergolide concentration.

On Day 0, concentrations of the compounded pergolide liquid ranged from 57-95% of the labeled concentration of 1 mg. By Days 30 and 60, the concentrations had further dropped to 51-82%, and 38-70%, respectively, of the original labeled concentration (1 mg).



On Day 0, concentrations of the compounded pergolide powder ranged from 32-107% of the labeled starting concentration of 1mg. By Days 30 and 60, the concentrations had further dropped to a range of 21-105%, and 18-75% respectively, of the original labeled concentration (1 mg).

Conclusions:

- On Day 0, only three compounded formulations tested met FDA standards for potency.*
- At the end of the 60 Day testing period, none of the formulations met FDA standards for potency.*
- Regardless of the formulation, all compounded pergolide concentrations decreased from a minimum of 25% to a maximum of 82% of the original labeled concentration (1mg) by Day 60.

*(+/-10% labeled concentration)

1) Stanley SD and Knych HD. Comparison of pharmaceutical equivalence for compounded preparations of pergolide mesylate. *AAEP Proceedings* 2010; (56): 274-276.