Potency vs. Time Stability Study
Albuterol/ Budesonide/ Ipratropium Bromide

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Abstract

The concentration of a compounded preparation of Albuterol, Budesonide, and Ipratropium Bromide was analyzed over a period of 219 days to determine the potency change.

Purpose

The purpose of this project is to determine whether the potency of Albuterol, Budesonide, and Ipratropium Bromide was affected by time.

Conditions

•The tested compounded preparation consisted of three active ingredients:

-Albuterol @ 2.5mg/ 3ml

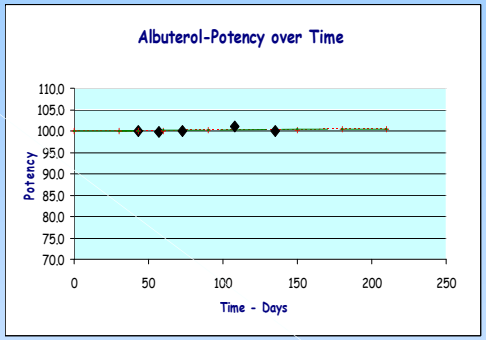
-Budesonide @ 0.25mg/ 3ml

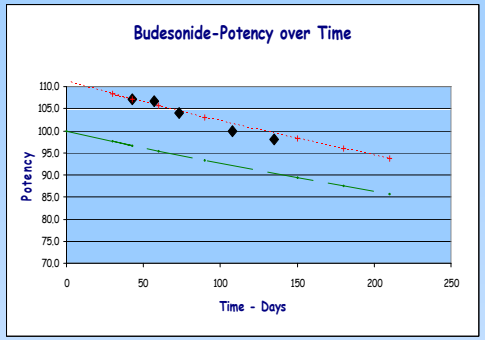
-Ipratropium Bromide @ 0.5mg/ 3ml

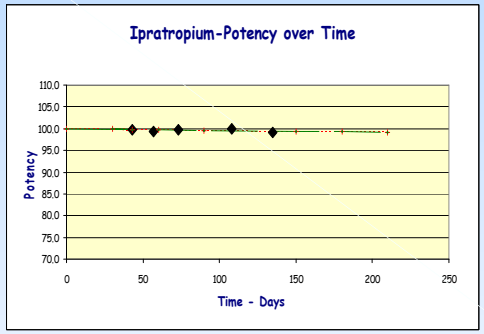
•The preparation was provided in plastic inhalation vials, stored at room temperature (22°C), and at 50-60% humidity.

•Vials were protected from light in an amber bag, and stored in a laboratory cabinet.

Results







*Black is Experimental, Red and Green are Forecast

Method of Analysis

•Dilution ratio was calculated to give a final concentration of 100 µg/ml of the active.

•Sample was withdrawn from a previously unopened vial, and three quantitative dilutions were made for each active ingredient.

•Samples were analyzed using a High Performance Liquid Chromatograph with Photo Diode Array detectors. These detectors allow a look within the chromatograph peak to determine if a interfering breakdown product is hiding there.

•Samples are then compared with standard samples of the active at a concentration of 100µg/ml

Conclusion

Analysis of all three drugs (Albuterol, Budesonide, and Ipratropium Bromide) showed that time did not have a significant effect on the potency of the drugs throughout the 219 day study. Results show that the potency of all drugs remained within the USP guideline of 100% +/- 10%

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Credits

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