Potency vs. Time Stability Study

Morphine Sulfate/ Bupivacaine HCl/ Clonidine HCl

Richard B. Moon, PharmD, RPh, FIACP

Pharmacy Innovations- Jamestown, NY

Introduction

The concentration of a compounded preparation of Morphine Sulfate, Bupivacaine HCl, and Clonidine HCl was analyzed over a period of 184 days (from compounding) to determine the potency change.

Purpose

The purpose of this project was to determine whether the potency of Morphine Sulfate, Bupivacaine HCl, and Clonidine HCl was affected by time.

Conditions

•The tested compounded preparation consisted of three active ingredients:

Morphine Sulfate @ 18mg/ ml

Bupivacaine HCl @ 18mg/ ml

Clonidine HCl @ 0.025mg/ ml

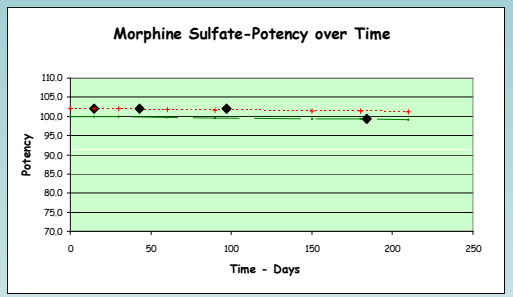
•The preparation was provided in a crimp top glass vial of approximately 10ml volume.

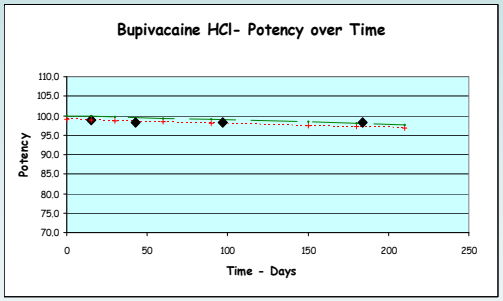
•For testing, the preparation container was opened, a sample withdrawn, and resealed until time of analysis.

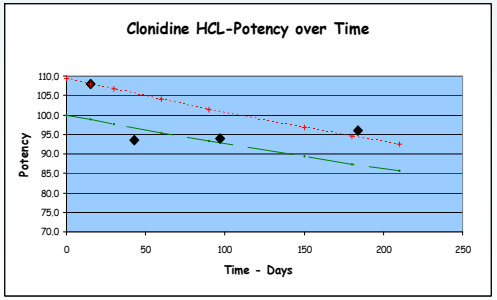
•The vials were stored at room temperature (22° C), and relative humidity between 50%-60%

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

Results







Black is Experimental; Green and Red are Forecast

Methods

•For the Morphine Sulfate and Bupivacaine HCl, a sample was withdrawn from the vial

•A quantitative dilution was made, one for each active ingredient.

•The dilution ratio was calculated to give a final concentration of 100 µg/mL of the active.

•The Clonidine HCl was analyzed undiluted.

Conclusion

Analysis of all three drugs (Morphine Sulfate, Bupivacaine HCl, and Clonidine HCl) provided evidence that time did not have a significant effect on the potency of the drugs throughout the 184 day study. Results show that the potency of all drugs remained within the USP guideline of 100% +/- 10% for the duration of the test.

Contact Information

Richard B. Moon, PharmD, RPh, FIACP
Pharmacy Innovations
863 Fairmount Ave
Jamestown, NY 14701
Phone: (716) 484-1586
www.pharmacyinnovations.net

Credits

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