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• For testing, the preparation container was opened, a sample withdrawn, and resealed until time of analysis.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

- Morphine Sulfate-Potency over Time
- Bupivacaine HCl- Potency over Time
- Clonidine HCl- Potency over Time

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.

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Credits

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