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A Modified Potency Test Strategy for IV Admixtures Prepared by Robotic Systems

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Abstract

Introduction:

Robotic systems are increasingly used for compounding sterile IV admixtures (1-5). In addition to routine gravimetric checks, initial and periodic drug potency analysis by high-performance liquid chromatography (HPLC) is desired to verify the system accuracy. However, the conventional HPLC test procedures often result in unexpected failures (1-2).

This study was initiated to develop a modified HPLC test strategy to eliminate the common source of variability and focus the effort on the accuracy of robotic system.

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Comments

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A Modified Potency Test Strategy for IV Admixtures Prepared by Robotic Systems

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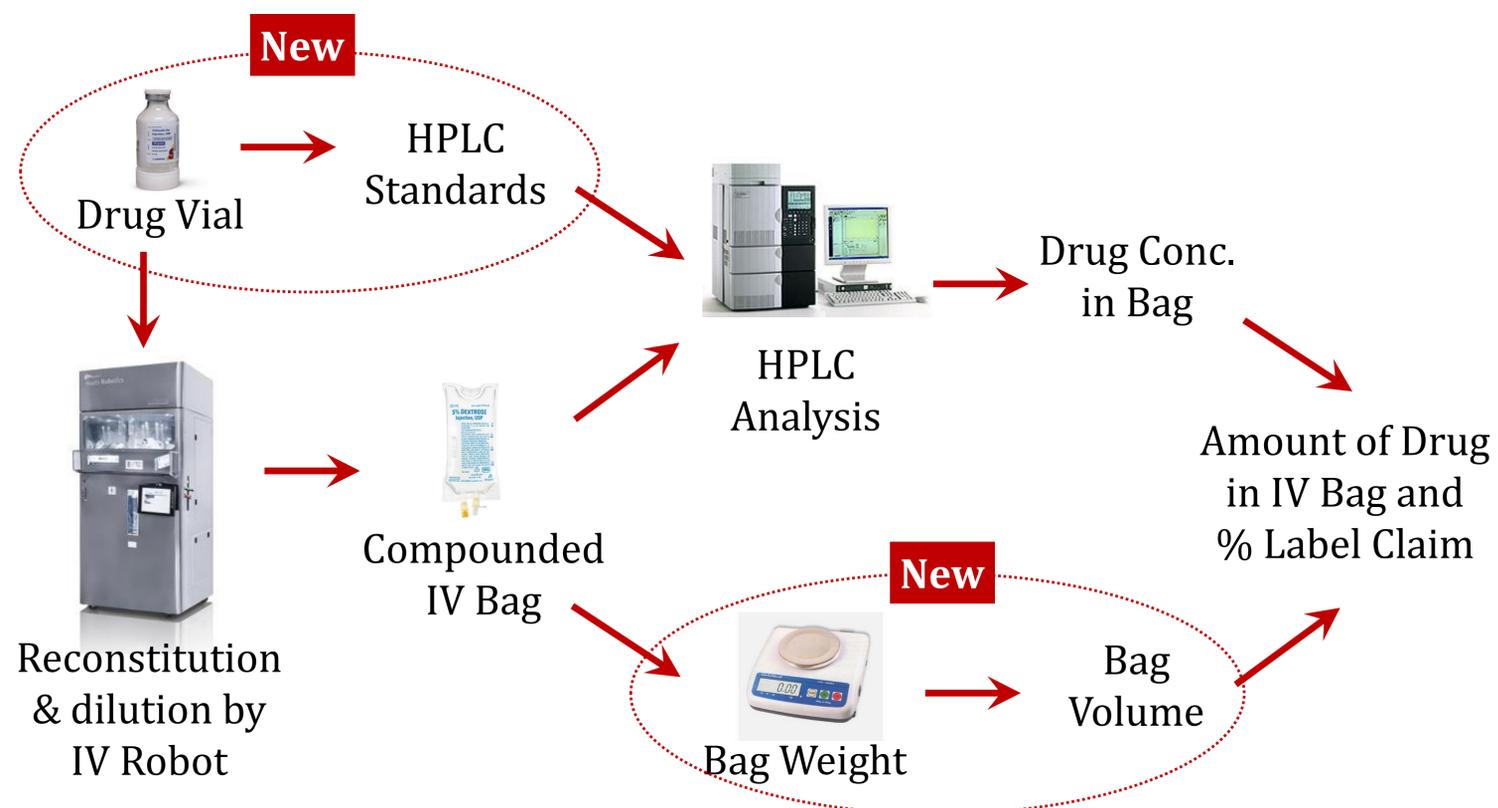


Presented at 2015 AACP Meeting

Introduction

Robotic systems are increasingly used for compounding sterile IV admixtures (1-5). In addition to routine gravimetric checks, initial and periodic drug potency analysis by high-performance liquid chromatography (HPLC) is desired to verify the system accuracy. However, the conventional HPLC test procedures often result in unexpected failures (1-2).

This study was initiated to develop a modified HPLC test strategy to eliminate the common source of variability and focus the effort on the accuracy of robotic system.



Methods

Two i.v.Station™ robotic systems were used to prepare IV bags for four representative drug products, i.e. cefazolin, ceftriaxone, penicillin G, and epinephrine. The first three products required reconstitution prior to dilution to iv bags. Six bags (n=6) were prepared for each drug product and for each robotic system.

As shown in the schematic above, two new approaches were employed in the HPLC potency analysis to eliminate variability unrelated to robot performance. First, the HPLC standards were prepared from the source drug vials rather than the pure drug substances. Second, the content of each bag was accurately weighed and converted to volume based on fluid density. Subsequent sample dilution and HPLC analysis were carried out following conventional practice.

The passing criteria for the robotic systems were: (a) amount of drug in each bag was within 90-110% nominal value, and (b) the 95% confidence interval (CI) of the mean is within 90-110% nominal value.

Results and Discussion

- The new HPLC potency test strategy was executed, and both IV robotic systems met the passing criteria.
- For all products, the amount of drug in each bag ranged from 95.0 to 105.9% nominal value, and the 95% CI of the mean ranged from 93.2 to 107.5%.
- All IV bags were found to contain 9-18% overfill. This would have significantly skewed the potency data if not factored in the calculation.

Conclusions

- A modified HPLC potency test strategy has been developed and implemented successfully for two IV robots with four representative drug products.
- The HPLC potency test provides an orthogonal method to gravimetric checks for verifying robot accuracy.

References

1. Nurgat Z et al. A three-year study of a first-generation chemotherapy-compounding robot. *Am J Health-Syst Pharm.* 2015; 72:1036-45.
2. Masini C et al. Automated preparation of chemotherapy: quality improvement and economic sustainability. *Am J Health-Syst Pharm.* 2014; 71:579-85.
3. Yaniv AW, Knoer SJ. Implementation of an i.v.-compounding robot in a hospital-based cancer center pharmacy. *Am J Health-Syst Pharm.* 2013; 70:2030-7.
4. Seger AC et al. Impact of robotic antineoplastic preparation on safety, workflow, and costs. *J Oncol Pract.* 2012; 8:344-9.
5. Volpe G et al. Robotics in acute care hospitals. *Am J Health-Syst Pharm.* 2012; 69:1601-3.