GETTING THE DOSE RIGHT: EVALUATING CONSISTENCY IN ORAL COMPOUNDING

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Background

Extemporaneous oral compounding remains a critical practice within hospital pharmacy, particularly for pediatric and geriatric patients who often lack access to suitable commercial liquid formulations. Variability in dose uniformity across compounded preparations represents a major safety challenge and can negatively impact therapeutic effectiveness. SyrSpend® SF has gained relevance as a standardized suspending vehicle due to its chemical inertness, controlled viscosity and broad compatibility with diverse active pharmaceutical ingredients.

Aim and objectives

The aim of this study was to evaluate the content uniformity and chemical stability of a wide range of extemporaneously compounded oral suspensions prepared with SyrSpend® SF PH4 liquid and SyrSpend® SF Alka. By assessing multiple APIs under different storage conditions and timepoints, the study sought to determine whether a standardized vehicle can reliably support consistent dosing performance and enhance safety in hospital pharmacy compounding practice.

Material and Methods

A total of 180 oral suspensions, containing 127 different active pharmaceutical ingredients (APIs) were prepared using standardized procedures and SyrSpend® SF PH4 liquid (for acid-stable APIs) or SyrSpend® SF Alka (for acid-labile APIs) as suspending vehicle. Samples were stored under room-temperature and refrigerated conditions and analyzed on Days 0, 7, 14, 30, 60, and 90. Prior to each sampling point, containers were manually shaken to simulate patient handling, and six aliquots were collected from the center of each bottle. In total, 11,400 analytical determinations were included in the final content-uniformity dataset. Analyses were performed using validated stability-indicating HPLC-UV methods supported by forced-degradation studies. Content-uniformity assessment followed compendial criteria, including L1 (± 15%) and L2 (± 25%) limits aligned with USP <905> and BP requirements for liquid dispersions.

Results

All formulations complied with USP and BP requirements for content uniformity under both room-temperature and refrigerated storage. Average recovery values were 99.81% at room temperature and 100.21% under refrigeration, with concentration ranges from 90.86% to 109.91% of label claim across all APIs (Figure 1). No formulation exhibited instability or deviations exceeding pharmacopeial limits over the 90-day period, demonstrating that SyrSpend® SF provides consistent dosing performance across a broad spectrum of active ingredients.

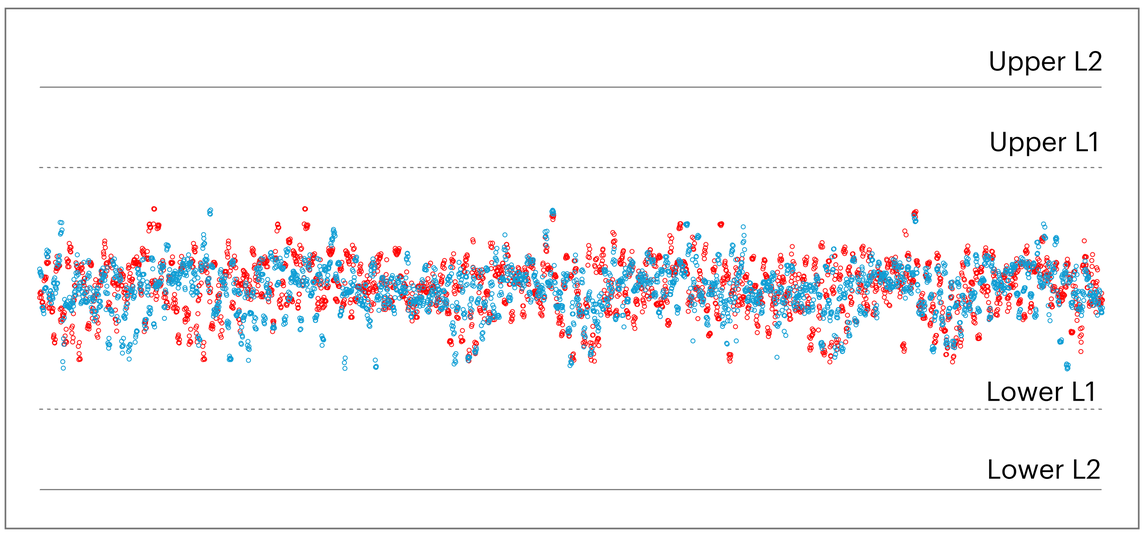

Figure 1. Content uniformity. Blue = refrigerated; red = room temperature. L1 ±15%, L2 ±25%

Discussion

The findings demonstrate that using a standardized vehicle such as SyrSpend® SF significantly reduces formulation-related variability in extemporaneous compounding. The consistent performance observed across different APIs and storage conditions underscores its relevance for improving the reliability of dosing, particularly for vulnerable populations such as children and the elderly. By supporting reproducible compounding workflows and aligning with pharmacopeial expectations, this vehicle enhances safety, therapeutic predictability and institutional quality assurance

Conclusion

SyrSpend® SF proved to be a highly reliable vehicle for extemporaneous oral suspensions, ensuring consistent content uniformity and chemical stability across a wide variety of APIs and storage conditions. These results support its adoption as a standardized vehicle within hospital pharmacies seeking to reduce variability, enhance patient safety and improve the reproducibility of compounded preparations.

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