CONTENT UNIFORMITY OF EXTEMPORANEOUS COMPOUNDED SUSPENSIONS

E. DIJKERS[1], H. POLONINI[2], A. FERREIRA[2]

[1]GLOBAL INNOVATION PROJECT MANAGER, FAGRON BV, ROTTERDAM, THE NETHERLANDS.

[2]ORTOFARMA ANALYTICAL SERVICES, MATIAS BARBOSA, BRAZIL.

Conclusion

Compounded oral liquids in SyrSpend® SF showed little variation in content for all Active Pharmaceutical Ingredients (APIs).

When evaluated according to the pharmacopoeia Content Uniformity guidelines, all were well within the criteria defined.

This indicates that compounding oral liquids in SyrSpend® SF could be a suitable alternative when compounding individualised medication for patients.

Materials and methods

In the study, 6.414 samples were analysed by High Performance Liquid Chromatography (HPLC-UV) for 105 Active Pharmaceutical Ingredients (APIs) at refrigerated temperature (2-8 ºC) and 93 different Active Pharmaceutical Ingredients at controlled room (20-25 ºC).

Calculations were only performed until the maximum beyond-use date of the sample.

Acceptance Values (AVs) were calculated for all the different Active Pharmaceutical Ingredients, at all time-points and temperatures.

Results

The mean Acceptance Value for room temperature and controlled refrigerated temperature was 3.12 and 3.17, respectively (Acceptance Value should be less than 15.0), indicating that all Active Pharmaceutical Ingredients comply with the EP/USP Content Uniformity specifications.

When evaluated according to the BP Content Uniformity of Liquid Dispersions, all Active Pharmaceutical Ingredients were well within the first range (85%-115% of the declared content). The mean concentration of all samples was 100.30% at room temperature and 100.34% at refrigerated temperature.

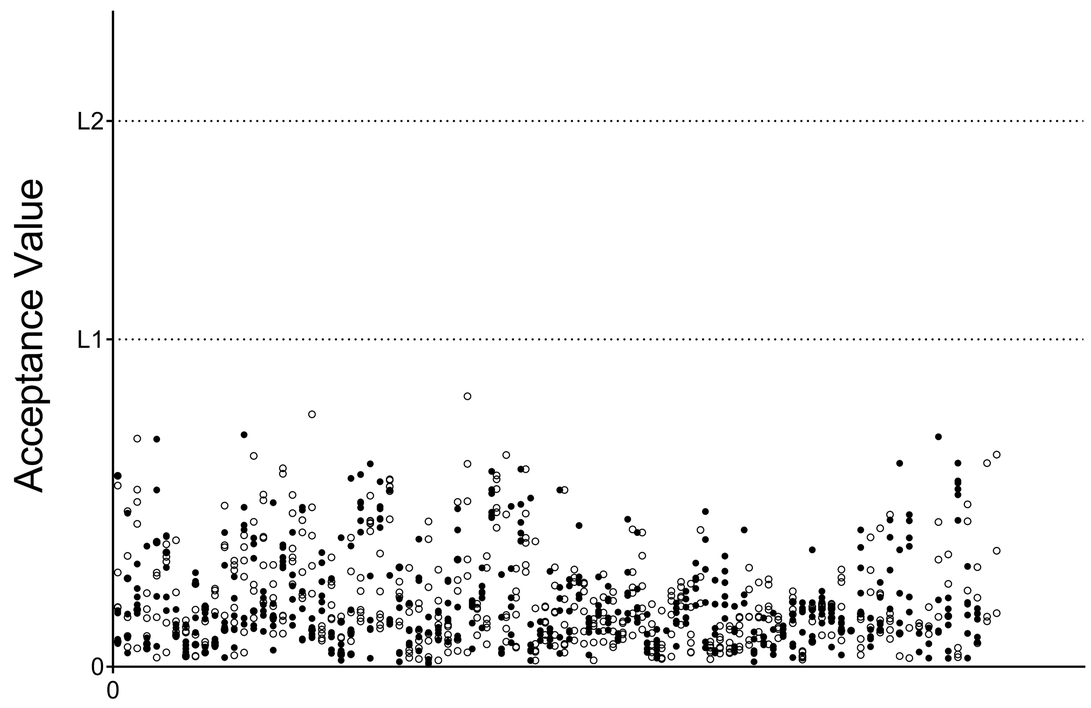
Introduction

There is still a need for non-sterile compounded medication for paediatric and elderly patients, e.g. in case of dose adjustments or swallowing difficulties[1-3]

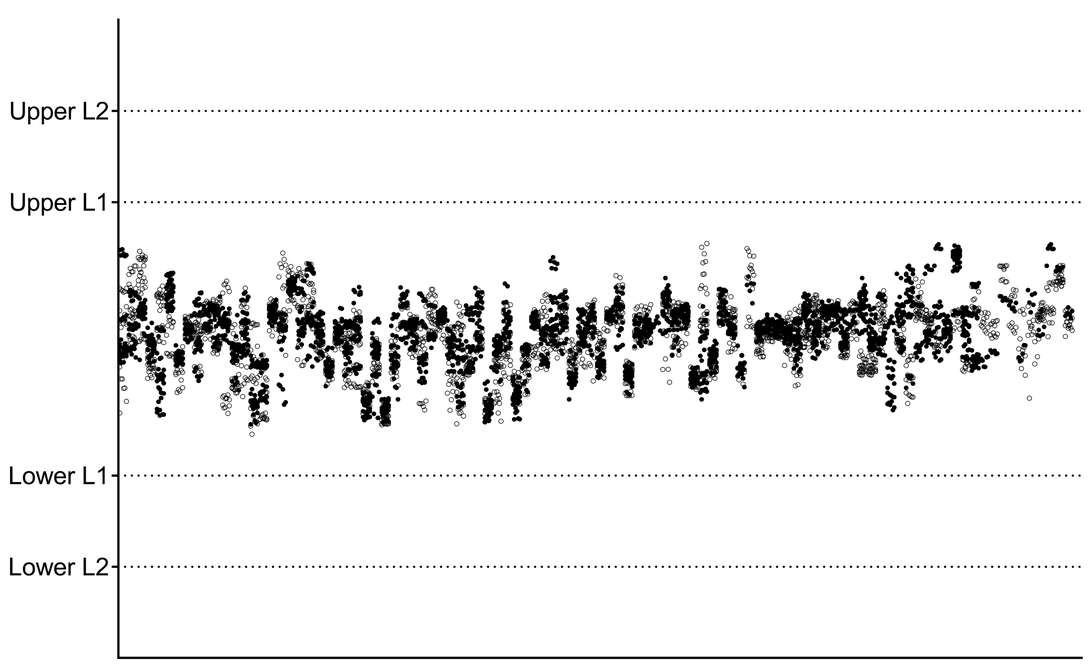
Pharmacists generally have the choice between compounding capsules or oral liquids. Extemporaneous compounded oral liquids are often a more convenient and better adhered alternative to capsules, as they are swift to prepare and can allow dosing flexibility.

Given their importance, drug substance content should be within the predetermined range, determined as Content Uniformity, as defined by USP, EP AND BP.

Content Uniformity according to USP and EP



BP Content Uniformity of Liquid Dispersions



Literature cited

1. Ivanovska V, Rademaker CMA, van Dijk L et al. Pediatric Drug Formulations: A Review of Challenges and Progress. Pediatrics 2014; 134(2): 361–372.

2. Kearns GL et al. Developmental pharmacology—drug disposition, action, and therapy in infants and children. N Engl J Med 2003;349:1157-67.

3. Schirm E et al. Lack of appropriate formulations of medicines for children in the community. Acta Paediatr 2003; 92: 1486-1489

V03 All other therapeutic products
Abstract nr 3PC-034

Further information
For further information, please contact
eli.dijkers@fagron.com

Fagron
personalizing medicine