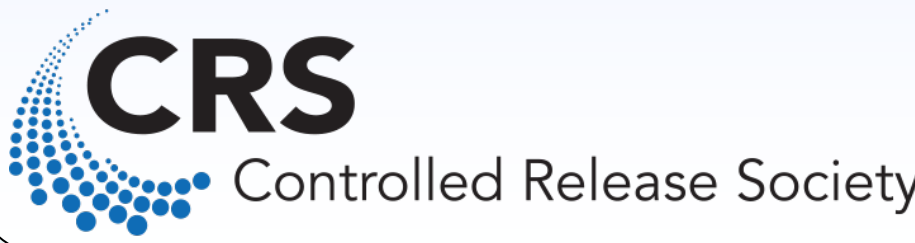


Alternative Reconstitution Soft Foods Vehicles for Sodium Oxybate Extended-Release Drug Product (LUMRYZ™)

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INTRODUCTION

Sodium Oxybate Extended-Release Drug Product (LUMRYZ™) is a once-nightly formulation of sodium oxybate containing both immediate release (IR) beads and pH-dependent controlled-release (CR) beads, designed to be reconstituted in water and administered orally. A study was conducted to determine the dissolution profile and pH of LUMRYZ™ at prescribed doses after mixing with soft food vehicles like pudding, applesauce and yogurt.

METHOD

The lowest dose (4.5 g) and the highest dose (9 g), single-dose drug packs, were reconstituted in Milli-Q water (control (CL)), **Lemon Pudding** (LP), **Applesauce** (AS), and **Vanilla Lowfat Yogurt** (YO). The reconstituted mixtures were tested for dissolution and pH. The dissolution was measured at 15 minutes and 2, 2.5, 3, 4, 5 hours after mixing by shaking and 5-minute rest period. The pH of each mixture was measured prior to and after addition of the drug product.

RESULTS

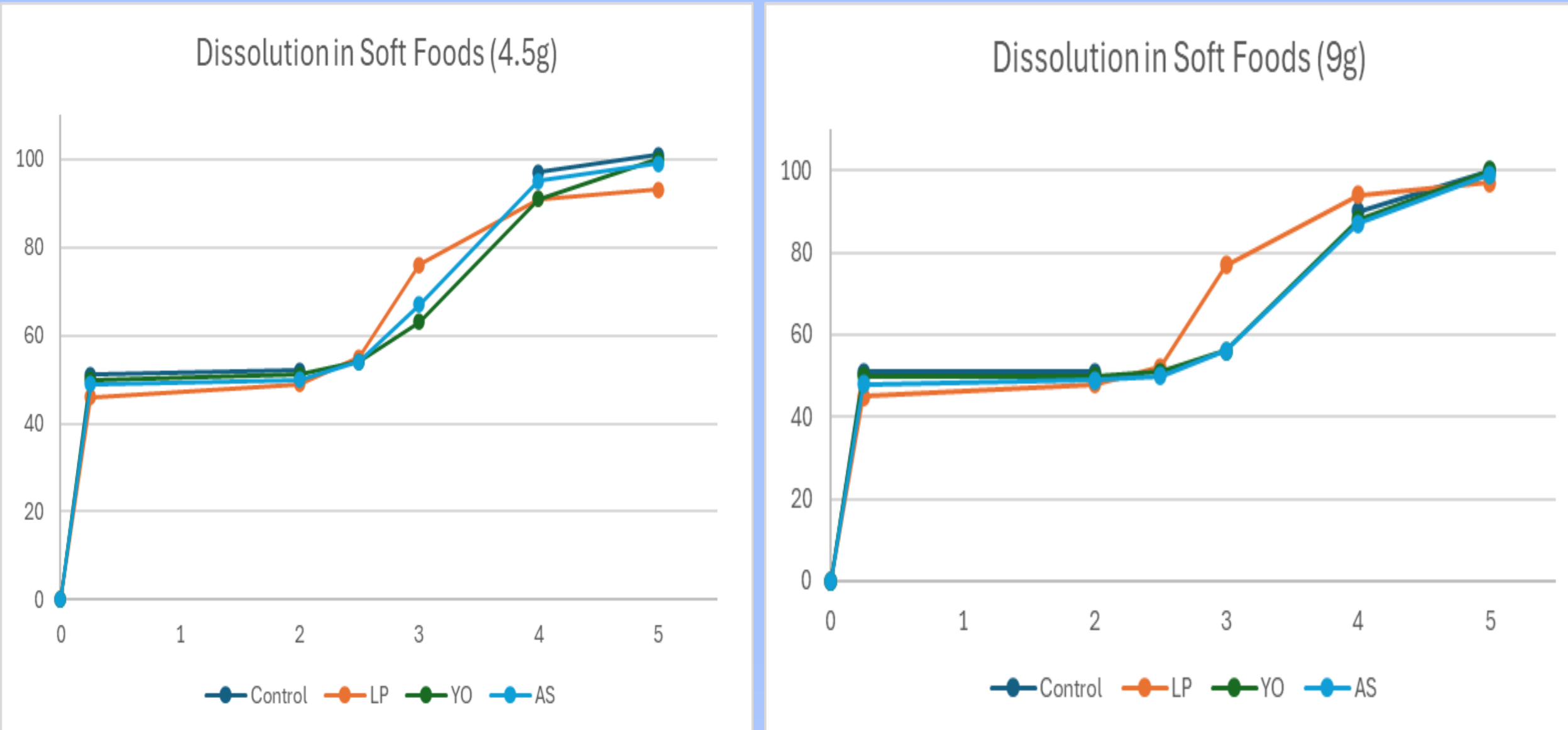


Figure 1. Drug Product Dissolution Profile – Soft foods in 4.5g and 9.0g.

The lowest dose (4.5 g) released 50% of its SO after 15 minutes in the CL, 48% in LP, 49% in AS and 50% in YO; at 5 hours, 101% was released in CL, 98% in LP, 99% in AS and 100% in YO. The highest dose (9.0 g) released 51% of its SO after 15 minutes in the CL, 45% in LP, 48% in AS and 50% in YO; at 5 hours, 100% was dissolved in CL, 97% in LP, 99% in AS and 100% in YO. The pH of LP, AS and YO, before the addition of the LUMRYZ™ was 3.6, 3.6 and 4.1, respectively. For the 4.5 g dose reconstituted in CL, LP, AS, and YO, the pH was 5.7, 5.3, 5.3, and 5.3 at 5 minutes respectively. For the 9.0 g reconstituted in CL, LP, AS, and YO, the pH was 5.8, 5.5, 5.5, and 5.5 at 5 minutes, respectively.

pH Results Summary			
Media	Pre-Sample Addition	Post-Sample Addition	
		4362012 (4.5 g)	4362023 (9.0 g)
Milli-Q	-	5.7	5.8
Pudding	3.6	5.3	5.5
Yogurt	4.1	5.3	5.5
Applesauce	3.6	5.3	5.5

Table 1.- The pH of LP, AS and YO, before and after the addition of the LUMRYZ™

CONCLUSIONS

The pH testing and the dissolution study demonstrated consistent and acceptable dissolution and pH results of the sodium oxybate extended-release drug product (LUMRYZ™) in various soft foods, which enables patients to safely and effectively use these alternative soft food vehicles for their preparation.

