OBJECTIVES
The purpose of this study is to determine the feasibility of encapsulating the Phosphatidylcholine based excipients Phosal® 53 MCT and Phosal® 50 PG into softgels and 2) to verify the stability and dissolution characteristics of the softgels after storage at one (1), two (2), and three (3) months at 40 °C/75% RH.

METHODS

Materials
- Phosal® 53 MCT and Phosal® 50 PG provided by Lipoid.
- 195 Acid Bone Gelatin purchased from Gelita.
- Peptide from Porcine Skin/Stomach mucosa purchased from Sigma.

Equipment
- 12 Obliging Premium Wall Dies.
- Hanson Stress/Fatigue Test Station.

Background
Phosphatidylcholine is a viscous low HLB surfactant. Phosal® 53 MCT consist of approximately 55/50 blend of Phosphatidylcholine and Medium Chain Triglycerides (MCT). Phosal® 50 PG is a blend of Phosphatidylcholine and approximately 37 Phospholipid (PG). Both the Phosal® 53 MCT and the Phosal® 50 PG excipients have been found to be excellent solvents for lipophilic water insoluble compounds. They have also been found to improve bioavailability of these compounds as a result of their surfactant properties, viscosity, and the PG content of the Phosal® 50 PG; these two (2) excipients are difficult to encapsulate into softgels. The Phosal® 53 MCT and Phosal® 50 PG softgels were manufactured on a Catalent 7th generation encapsulation machine using 12 Obliging premium wall dies. The gel mass formulations were chosen for compatibility with the fill formulation. The finished softgels were packaged into HDPE bottles and stored for the (3) months at 40 °C/75% RH. Qualitative dissolution was assessed by recording the time the softgel first visually opened and the time the fill was 100% visually dispersed in the dissolution medium. Dissolution was performed in 100 ml of Simulated Gastric Fluid (without enzymes) at 37.5 °C, with paddle speed at 100 RPM. The results of the qualitative dissolution are provided in Table 3 and Figure 1. There were no leakers or misshapen softgels found in the HDPE bottles during the study. There were no signs of cross-linking of the softgels or an unexpected increase in the opening time of the softgels. Pictures of the Phosal® 53 MCT softgels after storage at one (1), two (2), and three (3) months are shown Picture 2, Picture 3, and Picture 4, respectively.

RESULTS
Lot TS-10-028A
Approximately 15,000 Phosal® 53 MCT softgels were manufactured in Catalent’s St. Petersburg, Florida production facility as lot TS-10-028A. During the approximately two (2) hour run time, in-process fill weights, shell weights, and seal thicknesses were determined approximately every (1) minute. The results are provided in Table 1. During encapsulation, the softgels met the fill weight, shell weight, and seal thickness Acceptance Criteria.

CONCLUSIONS
Phosal® 53 MCT was successfully encapsulated into softgels using the 12-obliging premium wall dies and packaged into gel formulations. The softgels were stored in HDPE bottles for three (3) months at 40 °C/75% RH without any impact on the physical properties of the softgels (leakers, minor defects, and dissolubility characteristics) observed in the initial study. The results from this short study indicate that with the appropriate encapsulation machine set-ups, gel and gel formulation Phosal® 53 MCT can be a viable excipient for Pharmaceutical softgel products.