

Sorbitol Special®

Plasticizer in an Ibuprofen PEG-Based Formulation

Soft gels are highly popular dosage forms due to their appealing clarity and premium appearance. Nearly 90% of consumers said soft gels were easier to swallow than two-piece hard capsules. Most of those polled also said they believed soft gel products acted more quickly in the body compared to the other forms, and most state they would not have objections to paying a little more for products in soft gel versus other forms¹. As a result, OTC markets have found utility because of their appeal. One of the most popular products for soft gels is ibuprofen.

Ibuprofen Fill Preparation

Ibuprofen is slowly added to PEG 400 solution under 1000 rpm stirring. Stir for 15 minutes. KOH dissolved in water (cooled to room temperature after exotherm). To the ibuprofen PEG 400 solution, slowly add KOH solution stirring at 1000 rpm for 15 minutes. The label claim will state each 680mg of fill contains 350mg of ibuprofen with a target fill weight of 680mg as capsule fill.

Gel mass was aged for 17 hours to a viscosity around 13k cps. Gelatin capsules were cast to 0.82mm thickness, 12 minim ovals, and sealed at 37°C. Primary drying was done using a tumble drier for 60 minutes at 27°C and 32% RH. Secondary drying was done using tray drying for 72 hours at 20°C and 20% RH.

Table 1: Formulation Comparison for Sorbitol Special MDF85 with Ibuprofen Fill Preparation

Ingredient Name	mg/cap fill
Ibuprofen	350
PEG 400	200
Potassium Hydroxide	40
Water	90
Total	680

Three plasticizer systems were studied, SPI Pharma's Sorbitol Special, Sorbitol Special MDF 85, and a competitive system (Competitor P).

Figure 1: Total Water Content vs Drying Time For Three Plasticizer Systems

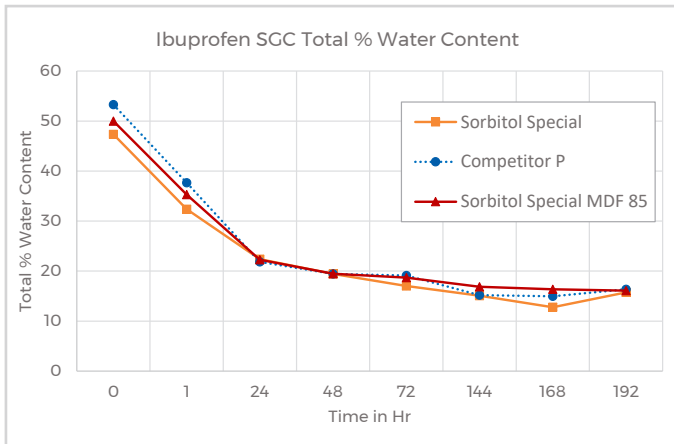
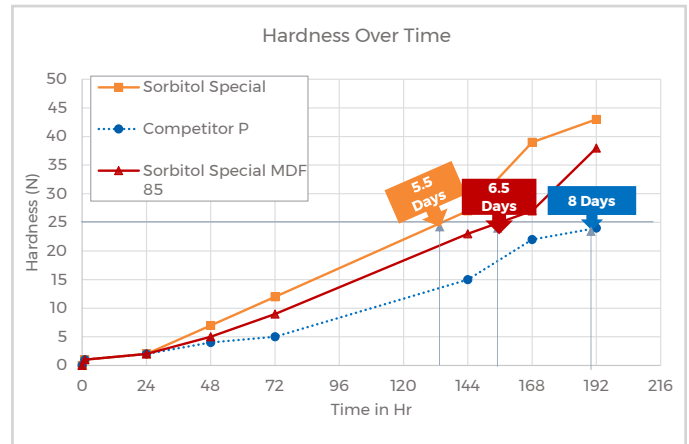


Figure 2: Evolution of Capsule Hardness vs Drying Time



All three plasticizers have very similar profiles in terms of the influence on total water content of the fill during drying.

SPI Pharma's Sorbitol Special and Sorbitol Special MDF 85 achieve a target hardness of 25N fastest.

Figure 4 provides a visual comparison made between the soft gel capsules using SPI Pharma's Sorbitol Special MDF 85 and Competitor P's plasticizer. It is evident that Sorbitol Special MDF 85 provides a more shiny, robust and rich soft gel capsule than other grades of plasticizer. With a more appealing appearance desired by consumers, manufacturers will appreciate the thicker coating, yielding less leakage, and faster drying times.

Figure 4: Ibuprofen Soft Gel Capsule 400mg Visual Comparison



Conclusion

SPI Pharma's Sorbitol Special helps increase production efficiency and provide a more appealing appearance desired by consumers. The use of Sorbitol Special for certain PEG based fill formulations can shorten drying times by up to 45% compared to alternative sorbitol based systems.

Reference

1. 2009 poll conducted by Expressions Planning Limited (Natural Products Insider 2019).

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