Sorbitol Special®

Soft Gel Plasticizer: Improved Drying Times

The formation of a soft capsule requires the use of a non-volatile plasticizer in addition to water to guarantee the mechanical stability. Sorbitol Special Plasticizers are engineered to counter-balance the stresses during processing and drying.

The production of soft gels first includes forming the soft gel, then the tumble and tray dry processes to harden. The majority of the production process for soft gel capsules is drying time.

Sorbitol Special MDF Drying Time in an Oil Filled Capsule

For most fill types, Sorbitol Special plasticizers can be used independently or with a glycerin system to reduce drying time.

Sorbitol Special and glycerin and a 50:50 combination were evaluated as plasticizers in capsules containing sunflower oil (model hydrophilic oil fill). The moisture level of the shell and the hardness development of the capsule with time was measured.

Methods and Materials

Gel mass was aged for 17 hours to a viscosity between 8k-10k cps. Gelatin capsules were cast to 0.85mm thickness, 12 Minim ovals, and sealed at 35.5°C. Primary drying was done using a tumble drier for 60 minutes at 23°C and 32% RH. Secondary drying was done using tray drying for 72 hours at 20°C and 20% RH Sorbitol Special + glycerol were mixed at 1:1.

Hardness was used to indicate the drying endpoint. Assuming capsule hardness target of 20N, Sorbitol Special plasticized capsules reach drying endpoint at 56% of the time it takes for glycerol, which is significantly faster.

Conclusion

Table 1: Gel Mass Composition

50:50 combinations of glycerol and Sorbitol Special attain capsule hardness faster than glycerol alone. Sorbitol Special can be combined with glycerin to modulate the overall plasticizer content in the formulation.

Ingredients% w/wGelatin (bloom 160)40Plasticizer20Water40Total100



Plasticizer	Drying Time (Hours)
Glycerin	64
Glycerin + Sorbitol Special	56
Sorbitol Special	36









Sorbitol Special MDF 85 Drying Time in PEG-Filled Soft Gels

Sorbitol Special MDF 85 and Competitor P were evaluated as plasticizers in capsules containing pure PEG (model hydrophilic fill). The processing and gel mass details are as given below. The moisture level of the shell and the hardness development of the capsule with time was measured.

Methods and Materials

Gel mass was aged for 17 hours to a viscosity between 9k-11k cps. Gelatin capsules were cast to ~0.85mm thickness, 12 Minim ovals, and sealed at 36.5°C. Primary drying was done using a tumble drier for 60 minutes at 23°C and ~30% RH. Secondary drying was done using tray drying for 72 hours at 20°C and 20% RH.

Hardness was used to indicate the drying endpoint. Assuming target hardness of 20N, Sorbitol Special MDF 85 would reach the target hardness 33% faster than Competitor P. This model exhibits significantly faster drying times than commercially available formulations which often contain water/potassium hydroxide and API. The absence of water improves the drying rate. In all cases, Sorbitol Special drives the increased dry rate in direct comparisons.

Conclusion

For oil and PEG model fills, Sorbitol Special plasticizers, either independently or with glycerin, reduce drying times and beat competitive materials. This yields an increased number of capsules at a faster speed, driving productivity and profit. Table 3: Gel Mass Composition

Ingredients	% w/w
Gelatin (bloom 160)	40
Plasticizer	20
Water	40
Total	100

Figure 2: Comparison of Capsule Hardness Development with Time





All information and statements given in this brochure are believed to be accurate at the time of publication. However, neither SPI Pharma nor any of their affiliates make any representations or warranty with respect thereto, including, but not limit to, any results obtained in the processing of the products by customers or any third party. All information and statements are intended for persons having the required skill and know-how and do not relieve the customer or user from verifying the suitability of information and statements given for a specific purpose prior to use of products. It is entirely the obligation of the costumer or user to comply with applicable laws and regulations, and also with all patent or other intellectual property rights of third parties.

SPI PHARMA EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND. WHETHER EXPRESS OR IMPLIED, AS TO THE ACCURACY, CURRENCY, COMPLETENESS AND/OR THE MERCHANTABILTY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY INFORMATION CONTAINED IN THIS BROCHURE AND/OR ANY PRODUCT DESCRIBED OR PROMOTED IN THIS BROCHURE, INCLUDING WARRANTIES WITH RESPECT TO INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER RIGHTS OF A THIRD PARTY. We reserve the right to change product specification and not specified properties of the products without prior notice.

> Order# SPI-EXC-SSP-0600-08201900 08-2019 | All rights reserved © 2019 SPI Pharma