Starch 1500®
Partially Pregelatinized Maize Starch

Colorcon®

Fluid-Bed Method for Increasing the Compactability of Echinacea Purpurea Powder Using Starch 1500® and Fumed Silica

Technical Data

Echinacea purpurea powder alone is poorly compressible. Tablets produced from the powder exhibit low tablet hardness values and are very friable. Treating Echinacea purpurea with Starch 1500 and fumed silica (Cab-o-sil) in the fluid bed was found to substantially increase the compressibility of the powder.

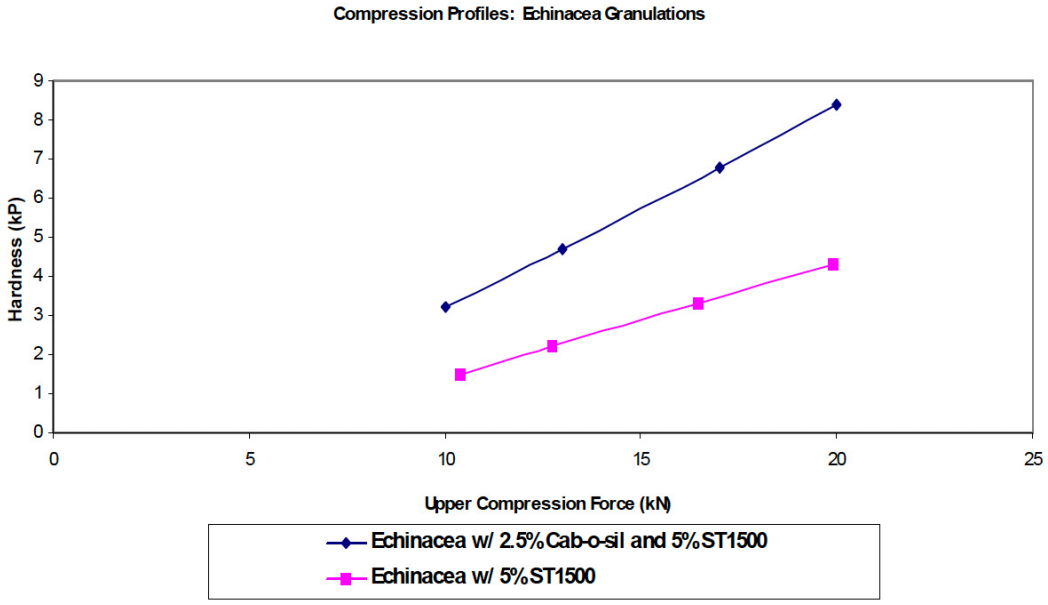
Blending Process

Two top-spray granulation methods were evaluated in a Glatt GPCG-3 fluid bed. The first trial consisted of 95% Echinacea purpurea powder and 5% Starch 1500. The Starch 1500 was sprayed onto the Echinacea as a slurry at a 6% solids concentration. The second trial was with a formulation containing 92.5% Echinacea purpurea powder, 2.5% fumed silica and 5% Starch 1500. The Echinacea was granulated by spraying on an 8.75% solids slurry of the Starch 1500 and fumed silica.

Both granulations were compressed on a Piccola 10 station rotary tablet press using 15/32" standard concave tooling. The target tablet weight was 385 mg.

Fluid-Bed Granulation Conditions (both batches)

Total batch size:	1300.0 g	**Atomizing air pressure:**	2.5 bar
Fluid delivery rate:	50 g/min	**Air flow:**	65 – 85 m^3/hr
Inlet air temperature:	55 °C during spray time		
	75 °C when drying		



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Granulation Results

Since Echinacea purpurea is basically not compressible on its own, the addition of Starch 1500 showed some improvement in the compressibility, while the addition of both Starch 1500 plus fumed silica showed an even more dramatic improvement. The Echinacea tablets made from the fumed silica and Starch 1500 granulations also had slightly lower friabilites (between 0.55 and 0.17%) while the tablets made from the granulation using strictly Starch 1500 had slightly higher friabilities (between 1.33 and 0.3%). Disintegration times for tablets made with both granulations were under a minute and a half.

Potency Analysis

Samples of untreated Echinacea purpurea powder, samples of both granulations and samples of tablets made from both granulations were sent to Hauser Laboratories (Boulder CO.) for HPLC analysis to determine total phenolic compounds, the markers for Echinacea. (*Total phenolic compounds are made up of the sum of the caffeoyl-tartaric acid and cichoric acid concentrations in each sample.*)

Sample ID	Caffeoyl-Tartaric Acid	Cichoric Acid	Total Phenolic Compounds
Echinacea Purpurea Powder	0.9% w/w	1.2% w/w	2.1% w/w
Echinacea w/ 2.5% fumed silica & 5% Starch 1500	0.8% w/w	1.0% w/w	1.8% w/w
Echinacea w/ 5% Starch 1500	0.73% w/w	0.87% w/w	1.6% w/w
Tablets made from Echinacea w/ 2.5% fumed silica & 5% Starch 1500	0.7% w/w	1.0% w/w	1.6% w/w
Tablets made from Echinacea w/ 5% Starch 1500	0.5% w/w	0.7% w/w	1.3%w/w

The results above show that treating the Echinacea purpurea powder to improve compressibility in a fluid bed process has little effect on the potency of the powder. However, the potency of the powder may be slightly affected by tabletting as the total phenolic compound assay is slightly lower for the tablets than the treated powder.

Conclusions

The treatment of Echinacea purpurea as discussed within this data sheet may be used to enhance the compactibility of the herbal powder prior to the addition of other excipients. This treatment can also be used in formulas where Echinacea is combined with other herbals.

In this study, a significant improvement in the compressibility of Echinacea powder was accomplished using Starch 1500 and fumed silica as a binder in the fluid-bed process. The finished tablets exhibited excellent hardness and friability. The tablets were then film coated with Opadry® II, producing a more elegant dosage form than the traditional capsules.

In addition to improving consumer acceptance of a product, the direct compression process may also increase the manufacturing efficiency over an encapsulation process. Encapsulation rates typically range between 1,300 to 2,000 capsules a minute compared to tablet manufacturing rates as high as 13,000 tablets per minute.

Traditional Dosage Form

Compressed to Tablet

Film Coated with Opadry® II

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