

Clear Coated Tablets with High-Solids Aqueous Starch Coating and Minimal Tablet Weight Gain

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PURPOSE

To study the use of a pregelatinized modified starch in a clear, aqueous film coating and the effect of minimizing tablet coating weight gain and maximizing coating solution solids on the quality of the finished tablet. Also, to determine potential savings in production time resulting from decreased tablet coating weight gain and/or use of a high-solids coating solution.

METHODS

A high-solids (16.5%), clear aqueous coating formula was compared to the same formula at a solids level more typically used (13.2%). The primary polymer was INSTANT PURE-COTE[®] B793 Pregelatinized Modified Starch NF from Grain Processing Corporation, Muscatine, IA, USA. Glycerin was used as the plasticizer at a 10% plasticizer to polymer ratio. Tablet cores tested were a lactose/microcrystalline cellulose placebo, a calcium supplement, a multi-vitamin supplement and an herbal supplement. The coating was applied to the cores to a weight gain of either a 0.5% level or a 1.0% level. Tablets were coated on a Vector Laboratory Development Coating System at Vector Corporation, Marion, Iowa, USA.

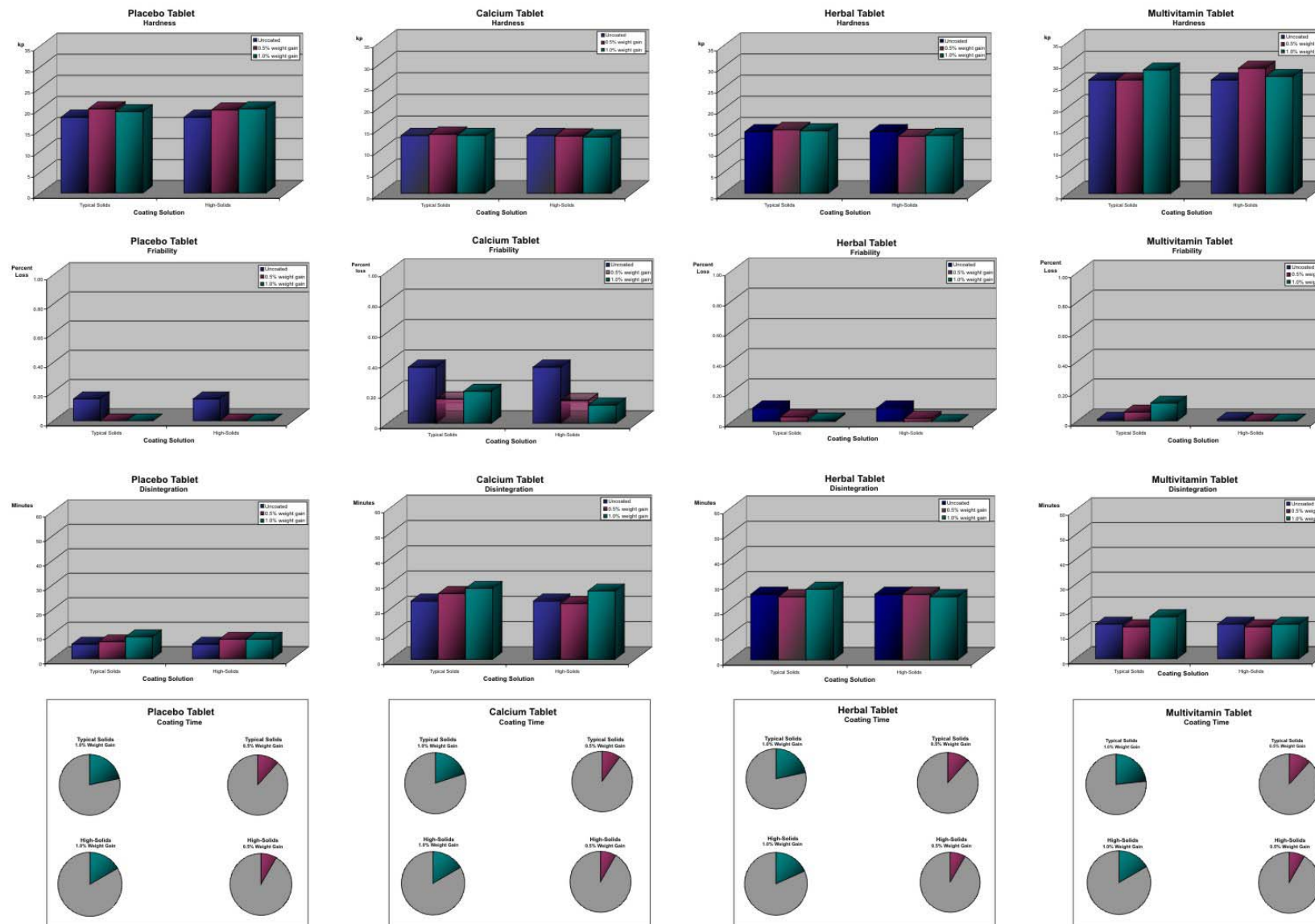
The coated tablets were tested for weight, thickness, hardness, friability and disintegration. Production time was recorded to evaluate the process efficiency when the weight gain of the coating applied to the tablet was decreased and/or when a high-solids formula was applied.

HIGH-SOLIDS FORMULATION

INSTANT PURE-COTE [®] B793	15.0%
Glycerin	1.5%
Total Solids	16.5%

TYPICAL SOLIDS FORMULATION

INSTANT PURE-COTE [®] B793	12.0%
Glycerin	1.2%
Total Solids	13.2%



RESULTS

Clear, aqueous tablet coatings using a typical solids INSTANT PURE-COTE[®] coating solution resulted in quality tablets at both the 0.5% and the 1.0% weight gain levels. Additionally, the high-solids INSTANT PURE-COTE[®] formula applied at either a 0.5% or 1.0% weight gain level resulted in a uniform, continuous, glossy, clear coating on the tablets.

The aqueous INSTANT PURE-COTE[®] coating did not decrease tablet hardness or increase tablet friability. As importantly, the disintegration time was not significantly affected by the coating.

By increasing coating formula solids from 13.2% to 16.5%, the desired weight gain was applied to the tablet cores faster resulting in a decrease in production time of approximately 25%. Furthermore, by reducing weight gain from 1.0% to 0.5%, the production time to coat the same amount of tablets was decreased by an additional 25% for a total production time reduction of about 50%.

CONCLUSIONS

An aesthetically pleasing, clear, aqueous tablet coating can be achieved using a high-solids coating formulation based on INSTANT PURE-COTE[®] B793 Pregelatinized Modified Starch NF. Uniform coatings were produced at application levels as low as 0.5% weight gain.

Using the high-solids coating formulation and the reduced tablet weight gain, the production coating time was greatly decreased, lowering overall production and coating costs. Tablet hardness, friability and disintegration were not significantly affected by the change in coating solution solids or tablet weight gain.

