Natural Enteric Coating With Charcoal-Decolorized Shellac

BACKGROUND
Shellac is the key to natural enteric coating. However, shellac has historically been unreliable for enteric coatings. The current method uses bleached shellac dissolved in an alcohol solvent. The solution is then applied as a pharmaceutical glaze. This type of enteric coating does not provide consistent enteric properties, particularly over time. This is largely due to the significant degradation of the shellac during the bleaching process. Additionally, the presence of alcohol leads to esterification and crosslinking of the bleached shellac. These phenomena have been strong obstacles to the development of natural enteric coatings.

PURPOSE
To demonstrate that a successful, stable, natural enteric coating system can be made from shellac using the appropriate materials and formulation.

METHODS
Orange shellac is used in an aqueous system. The shellac is charcoal decolorized rather than being bleached. The decolorized shellac is presented as the ammonium salt in water. Shellac is more stable in an aqueous system than in an alcoholic solution. Sodium alginate is used to lower the release pH of the film. Glycerin and maltin further stabilize and facilitate release of the coating. These four components can be sprayed from a 10% aqueous solution. The coating was applied to a 3% weight gain on both fish oil softgels and subcoated placebo tablets.

RESULTS
USP release characteristics were achieved. Coated softgels resist pH 1.2 buffer solution for one hour and disintegrate in pH 6.8 buffer solution in less than 30 minutes. The natural coating also maintained enteric properties on stability at both ambient and accelerated conditions. Tablets coated with this system achieve an enteric release with a variety of subcoats. Due to greater tablet surface area, smaller tablets require that additional coating be applied for the coating to be both functional and stable. Though the film swells in low pH solution, very little active is released.

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Coating on softgels and tablets passes the USP enteric test. Accelerated stability tests indicate a stable and reliable natural system has been developed.