One-Bucket Colored Coating Systems Based on [Poly [Butylmethacrylate-(-Dimethylaminoethyl) Methacrylate-Methylmethacrylate] 1:2:1]

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PURPOSE

The procedure currently recommended for formulating a color system with [Poly [Butylmethacrylate-(-Dimethyl-aminoethyl) Methacrylate-Methylmethacrylate] 1:2:1] (Eudragit EPO) involves successive additions of three powders to water; a separate addition of three or more ingredients to water; and finally the careful combination of both preparations. A one-bucket system would greatly reduce manufacturing process steps through the use of a pre-mixed value-added coating powder containing all necessary film components as a single ingredient.

Film Ingredients	%w/w
Eudragit EPO	53.4
Stearic Acid	8.2
Sodium lauryl sulphate	5.3
T	26.7
Titanium dioxide	4.3
Red iron oxide, or Blue #1 Lake	2.1

METHODS

All required ingredients for making a coating suspension using Eudragit EPO were combined together using Oster (feasibility scale) and PK (development scale) blenders. The basic blend components are Eudragit EPO, sodium lauryl sulphate at 10% of the EPO polymer, stearic acid at 15% of the polymer, and talc at 50% of the polymer (ratios taken from Degussa literature 3/2006). The pig-mented components are titanium dioxide at 8% of the polymer and various colorants at 4% of the polymer. The colorants used include red iron oxide, FD&C Blue #1 Aluminum Lake (high dye and low dye), and FD&C Yellow #6 Aluminum Lake (high dye).

These formulations are blended to make one-step dry coating blends, which are each reconstituted as a one-bucket system in deionized water at 16% solids mixing at a speed of not less than 1000rpm for 45 minutes. Formulations are screened prior to use with the residue (dried) reported as a percentage of the total solids. Coating suspensions were applied to tablets in fluid bed column coaters and in a 15 inch Thomas Engineering Accela-Cota perforated pan.

RESULTS

In all cases a coating system was formed which could be readily applied to tablets without gun-clogging or coagu-lation via aqueous film coating. Red iron oxide was applied in both types of coating equipment with no issues, even unscreened. The lakes left a screening residue of 0.7% of total solids (Blue 1 high dye), 0.4% (Yellow 6 high dye), and 0.0% (Blue 1 low dye).

Tablets coated with the red iron oxide EPO one-bucket system had an average disintegration time of 24 minutes in pH 6.8 phosphate buffer, and had an average disinte-gration time of two minutes in pH 1.2 simulated gastric fluid.

CONCLUSION

The ability to use Eudragit EPO as a single-bucket system will greatly reduce preparation times, production steps, and the number of raw materials required in production when using this polymer.

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