Scuffing Measurement Methodology and Improved Film Coating Systems

PURPOSE

Scuffing is a term used to describe coated tablet defects consisting of dark marks or streaks appearing on the face of tablets film coated with light or pastel colors.

Scuffing defects are thought to be caused by abrasion of the titanium dioxide pigment in the coating against the wall of a stainless steel coating pan as the tablets rotate. This may induce transfer of free metal oxide or other stainless steel surface contaminants onto the tablet face.[1] This problem does not seem to be specific to coating formulation type or polymer system. However, very smooth coatings with a low degree of tablet-to-tablet friction may exacerbate the problem. These tablets tend to slide rather than tumble along the side walls of the coating pan. Additionally, this problem is not seen in all coating pans indicating that the surface finish of the pan may be a contributing factor.[2] This surface finish problem is infrequent, intermittent in nature, and is difficult to troubleshoot and duplicate in a laboratory environment.

This study describes a laboratory test method to intentionally force tablet scuffing for the evaluation of pigment level modifications in coating formulations. Processing techniques to minimize scuffing of the finished product were also evaluated.

METHODS

Forced Laboratory Testing

In the laboratory scuffing test method, film coating formulations (PVA-based) with various levels of TiO_2 (anatase form) were evaluated. Standard round 9 mm placebo tablets, pre-coated to a 3% weight gain (WG), were placed in a 16” stainless steel conventional pan and rotated at 20 rpm. At five-minute intervals up to 30 minutes, all tablets were removed and visually inspected under magnification for scuffing related defects on both sides of the tablets. An acrylic box was constructed to facilitate the inspection of the tablets (Figures 1-4). The number of scuffed tablets per time point was plotted and compared for each formulation.

Figure 1. Photos of Tablets Tumbling in the Conventional Stainless Steel Pan

Figure 2. Example of a Scuffed Tablet

Figure 3. Apparatus for Inspection of Tablet Samples

Figure 4. Device for Presenting Tablet Samples for Inspection

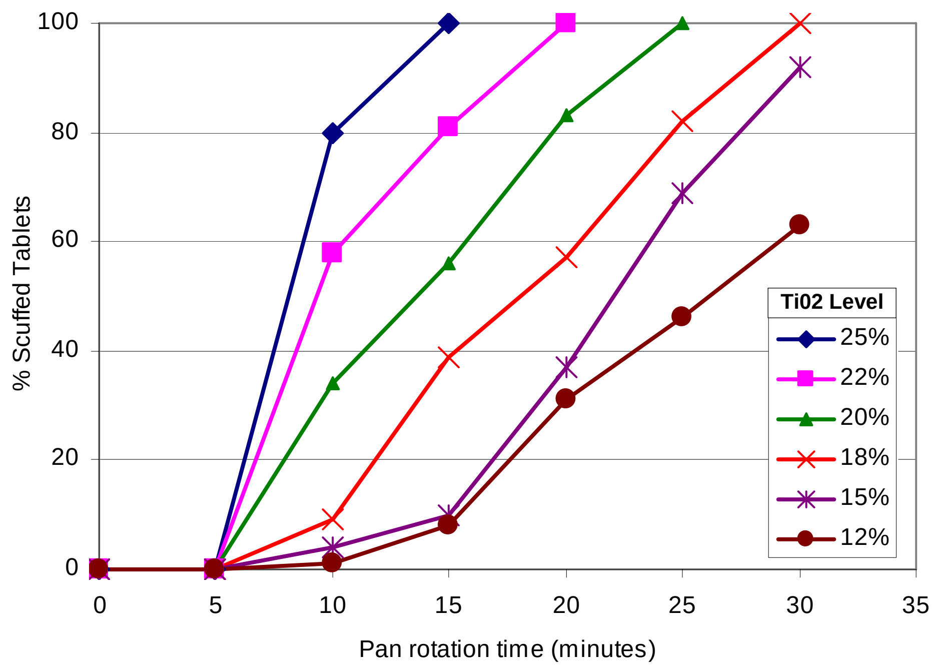
Actual Coating Trial Method

Separate, larger scale, coating trials were conducted on capsule shaped calcium tablets (1500 mg) in a 19" fully perforated, side-vented, coating pan with varying tablet charges, processing conditions (fluid delivery rates, coating temperatures), and formulations. The percentage of scuffed tablets from a representative sample of each trial was then determined. The large calcium tablets were chosen for the coating trials due to their high density and anecdotal evidence that larger, denser tablets seem to be more prone to scuffing.

RESULTS

Under the forced laboratory test conditions, scuffing defects decreased with reduced levels of titanium pigment in the film coating formulation. With every 3% decrease in pigment level, a 20% decrease in scuffing was observed (Figure 5).

Figure 5. Effect of TiO_2 Content on the Incidence of Scuffing in Test Environment

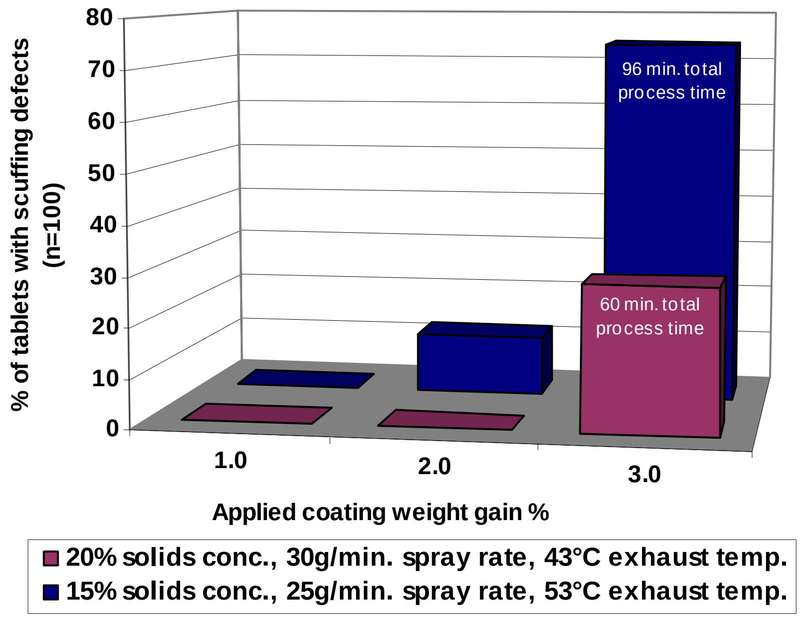


In this test environment, the tablets were simply tumbled and no actual spray was applied to the pre-coated tablets (as opposed to an actual coating environment). These test conditions resulted in much higher levels of scuffing than were observed in subsequent coating trials. The test did, however, demonstrate that adjustments in the level of TiO_2 in the coating formulation can significantly reduce scuffing tendencies.

Larger-scale coating trials, in terms of pan diameter and pan load, showed that irrespective of coating formulation used tablets from fully charged coating pans scuffed less than tablets from undercharged coating pans. However, in most cases the scuffing defects were barely discernable, variable, and extremely difficult to accurately quantify. This was particularly the case related to varying pan loads with other process conditions held constant. In these trials it was noted that the flow of the tablets in the undercharged pan exhibited a sliding motion against the walls of the pan while the tablets in the fully charged pan exhibited a more uniform tumbling motion. The sliding motion of the tablets in the under filled pan seemed to result in more scuffing defects.

More significant and quantifiable scuffing defects were obtained when examining other coating process conditions in the 19" pan (12kg tablet charge) using the coating formulation containing 25 % TiO_2. This TiO_2 level was the highest used in the conventional pan tumbling test. Cooler coating temperatures in combination with increased fluid delivery rates had a positive effect on minimizing incidence of scuffing (Figure 6).

Figure 6. Effect of Process Conditions on the Incidence of Scuffing



The data also show that the coating process time may be an important factor in the development of scuffing defects. Data from both the laboratory scuffing measurement method and actual coating trials indicate that the longer the tablets rotate in the pan, the greater the development of scuffing defects.

CONCLUSIONS

Coated tablet scuffing defects can be very difficult to troubleshoot and resolve due to the infrequent and variable nature of this problem. Three primary factors contribute to these scuffing defects; the coating process equipment, coating process conditions, and the coating formulation. All these factors should be assessed when investigating these defects.

From the coating equipment standpoint, the coating pan should be well cleaned and maintained. This will minimize any free metal oxide or other contaminants that could be abraded from pan surface and transferred to the coated tablet surface.

In the coating process, scuffing of film coated tablets can be reduced by using the maximum tablet charge for the coating pan and spraying at cooler bed temperatures or faster spray rates. It is very evident that minimizing the time that the tablets spend in the pan is important in reducing scuffing tendencies. This was shown in both the conventional pan forced laboratory test as well as in the actual coating trials.

Optimum coating formulations should be suitable for preparation at high solids concentration. This will reduce the amount of coating dispersion to be applied, the total coating time, and ultimately the degree of scuffing.

In this study, only the coating formulation containing the highest level of TiO_2 resulted in quantifiable levels of scuffing in the actual coating process. In cases where improved equipment maintenance and changes in coating process conditions do not resolve this scuffing, adjustment of the TiO_2 level in the coating formulation should be considered.

REFERENCES

1. Standard Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems, ASTM Standard A380-99 (2005).
2. Importance of Surface Finish in the Design of Stainless Steel, Dr. Colin Honess, Stainless Steel Industry, 15, August 2006.

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