Enteric Coating of Tablets with Debossed Logos

OBJECTIVES

Concerns over film uniformity and film defects have led to an avoidance of debossed logos on enteric coated tablets. The aim of this study is to demonstrate that careful selection of tablet shape, logo design and logo placement will result in a robust enteric coating and avoid the need to subject tablets to the printing operation.

METHODS AND MATERIALS

A direct compression blend was prepared comprising aspirin (Rhodine 2371, Rhodia, Cranbury, NJ), microcrystalline cellulose (Emcocel 90M, JRS Pharma, Patterson, NY) and stearic acid (Purified vegetable grade powder, Oleotec Ltd., London, England). Aspirin 325mg tablets were compressed to the same breaking force using round 0.4062” compound radius compression tooling with varying engraving styles and logo placement (Natoli, St. Charles, MO). The characters “ABC26” were chosen to represent a range of design complexity. The logos were placed centrally across the face of the tablet or around the perimeter of the tablet. A “single stroke cut” engraving style with a constant width, draft angle (40º), and depth, terminating with a full, single blend radius was compared to a “panel cut” with a flat area on the bottom surface. Plain, non-logo, tablets were also produced as a control.

Figure 1. Central Logo Placement

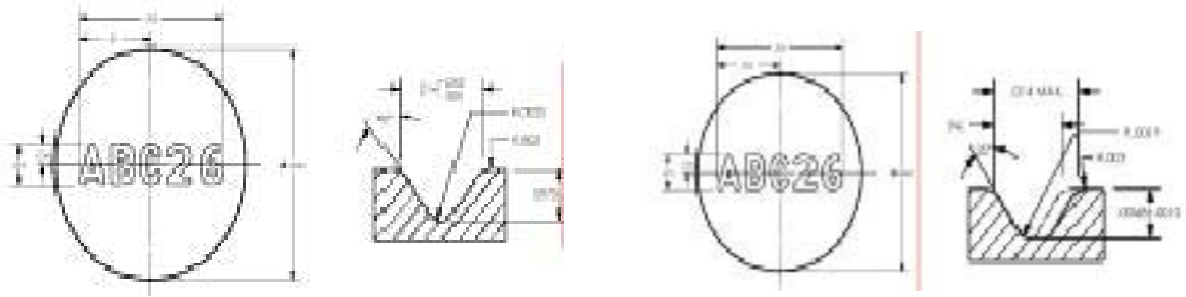
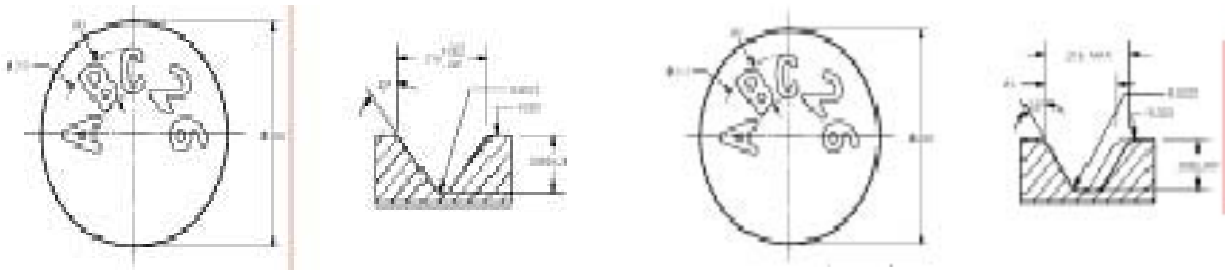


Figure 2. Perimeter Logo Placement



A fully formulated aqueous enteric coating system based on Eudragit L100-55* (Acryl-EZE, Colorcon, WestPoint, PA) and an aqueous film coating system (Opadry®, complete film coating system, Colorcon, West Point, PA) were used.

The delayed release coatings were carried out in a fully perforated, side-vented pan. Tablets were coated directly with the delayed release coating system or after the application of a 2.0% weight gain sub-coat. Tablet samples were taken at a theoretical 6, 7, 8, 9 and 10 % (4 and 5% with sub-coat) delayed release coating weight gain for enteric performance testing and examination of logo definition. Enteric performance (acid resistance) was assessed using a variation of the enteric disintegration method (European Pharmacopoeia 3rd Edition 2001 supplement). Six delayed release-coated tablets were individually weighed and subjected to 0.1N HCL for 2 hours. The tablets that were still intact were removed from acid and re-weighed to obtain the % acid uptake. Values less than 5% have been found to pass the acid phase of delayed release dissolution testing.[1]

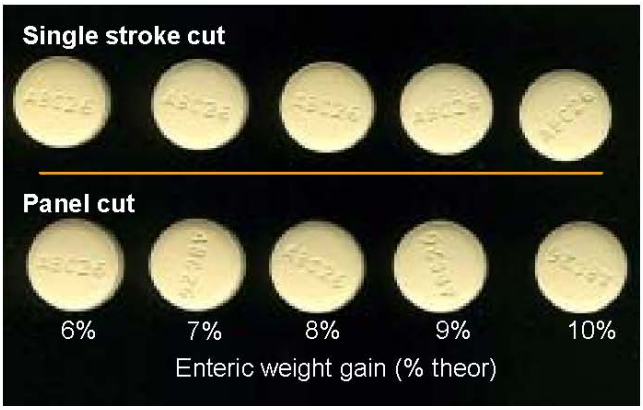
RESULTS

Visual examination of the tablets after coating revealed that good logo clarity was maintained up to the 10% delayed release coating weight gain studied. The clarity of the logos was consistent irrespective of the logo design type or placement.

Acid resistance testing showed that the tablets were robust and withstood acid penetration at less than the final delayed release coating weight gain of 10%. There was no difference in the results between the tablets of differing engraving styles or logo placement.

Figure 3. Logo Placement

Central – No Sub-coat



Perimeter – No Sub-coat

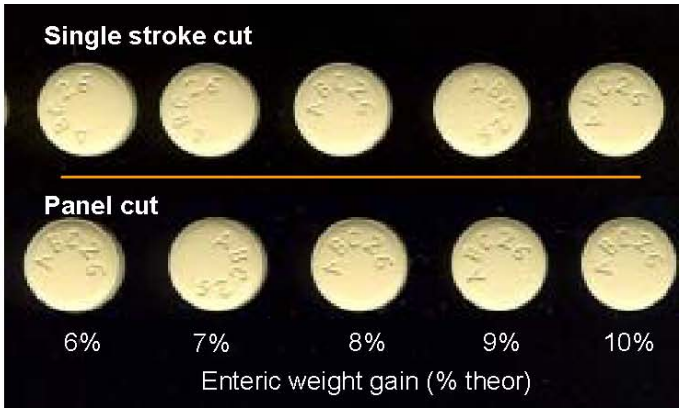


Figure 4. Acid Uptake Results – No Sub-coat

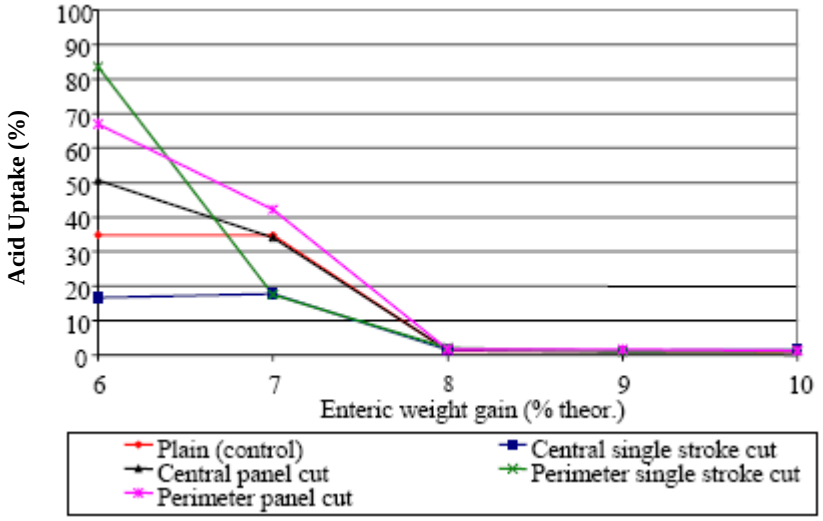
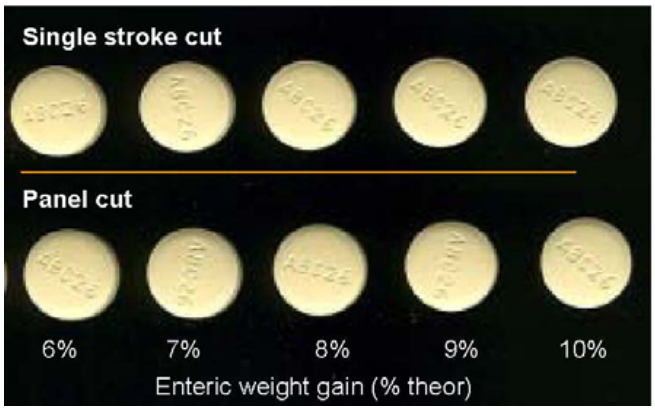


Figure 5. Logo Placement

Central – With Sub-coat



Perimeter – With Sub-coat

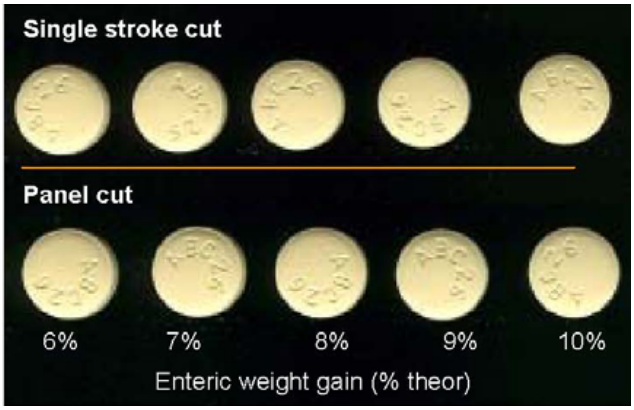
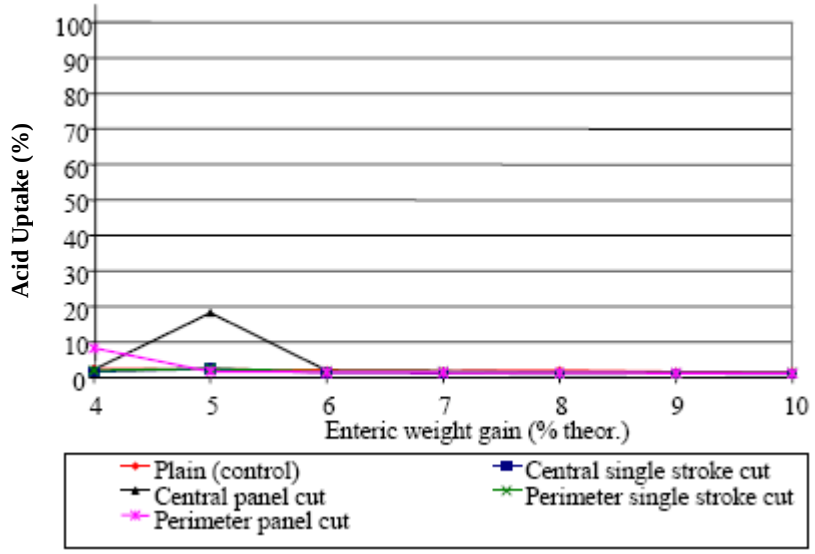


Figure 6. Acid Uptake Results – With Sub- coat



Failures that did occur were found at the edges of the tablets rather than the logos. At no point in testing were defects found within the logos that resulted in enteric failure as had been historically expected. It was also found that the application of a sub-coat made little difference in logo clarity but significantly reduced the quantity of delayed release coating needed for good acid resistance. Sub-coat application primarily adds strength to the outer edges of the tablet core and reduces edge related defects when the tablet mechanical strength is deficient.

CONCLUSIONS

The use of typical logo engraving styles and logo placement had no effect on acid resistance or clarity of logos. The delayed release coating system used in this study exhibited good adhesion characteristics further contributing to the clarity of the logos and good enteric protection. Edge wear was found to be the most critical factor in enteric performance.

Further processes for the branding and identification of tablets such as printing can be eliminated through proper selection of tablet shape, logo design and enteric coating system.

Adapted from the poster presented at CRS – Jul 2004.

References

1. Jordan, M.P., Taylor, J., Hadfield, P.J.; “A Comparison of the Performance Characteristics of Enteric Film Coating Systems”, Contributed paper, AAPS National Meeting, October (2001).

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