

Implementation of Quality by Design in Tablet Film Coating

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ABSTRACT

- Many tablets today are coated after being processed in pharmaceutical industry. Modern day drug delivery technique such delayed or extended release, aesthetic coating for brand identify and appeal to consumers are some of the reasons why tablets are film coating.
- Tablet film coatings are necessary for tablets for taste masking (medicinal taste) and a smoother finish makes tablets easier to swallow preventing dysphagia and improving patient compliance
- Tablet coatings are also useful to extend the shelf-life of components that are sensitive to moisture or oxidation.
- Tablet film coating is a critical manufacturing process step in drug development and product commercialization.

METHODS

- Many coating are polymer or polysaccharide based with plasticizers, opacifier, dye and colorants
- Opadry II coating powder (Colorcon) is dispersed in purified water at 12% w/w solids concentration.
- Round uncoated tablets (cores) are loaded into Flex 500 Accela Cota (Thomas Engineering) fitted with fully perforated 60" coating pan and rotated. The process conditions such as coating spray rate (g/min), coating pan speed (rpm), drying air temperature (C) and drying air flow rate (CFM) were recipe controlled through PC based automated tablet coating control system Compu-Coat® (Thomas Engineering) .
- The end point for film coating is the average weight gain (mg) of 3% w/w (Range 2-4%w/w) of the core tablet weight. Since most of the pharmaceutical operations are batch processes, there can be difference in end point achieved based on the quantity sprayed and processing condition such as humidity and dew point control.
- The critical quality attributes (CQAs) in this study were tablet coating visual defects such as peeling twinning, cracked tablets, color difference in order to achieve final weight gain.
- The coated tablets are dried and inspected. The average tablet weight gain (in mg) attained was plotted against the quantity of Opadry coating dispersion sprayed using JMP. Refer plot Quantity Sprayed vs. Weight Gain.

REFERENCES

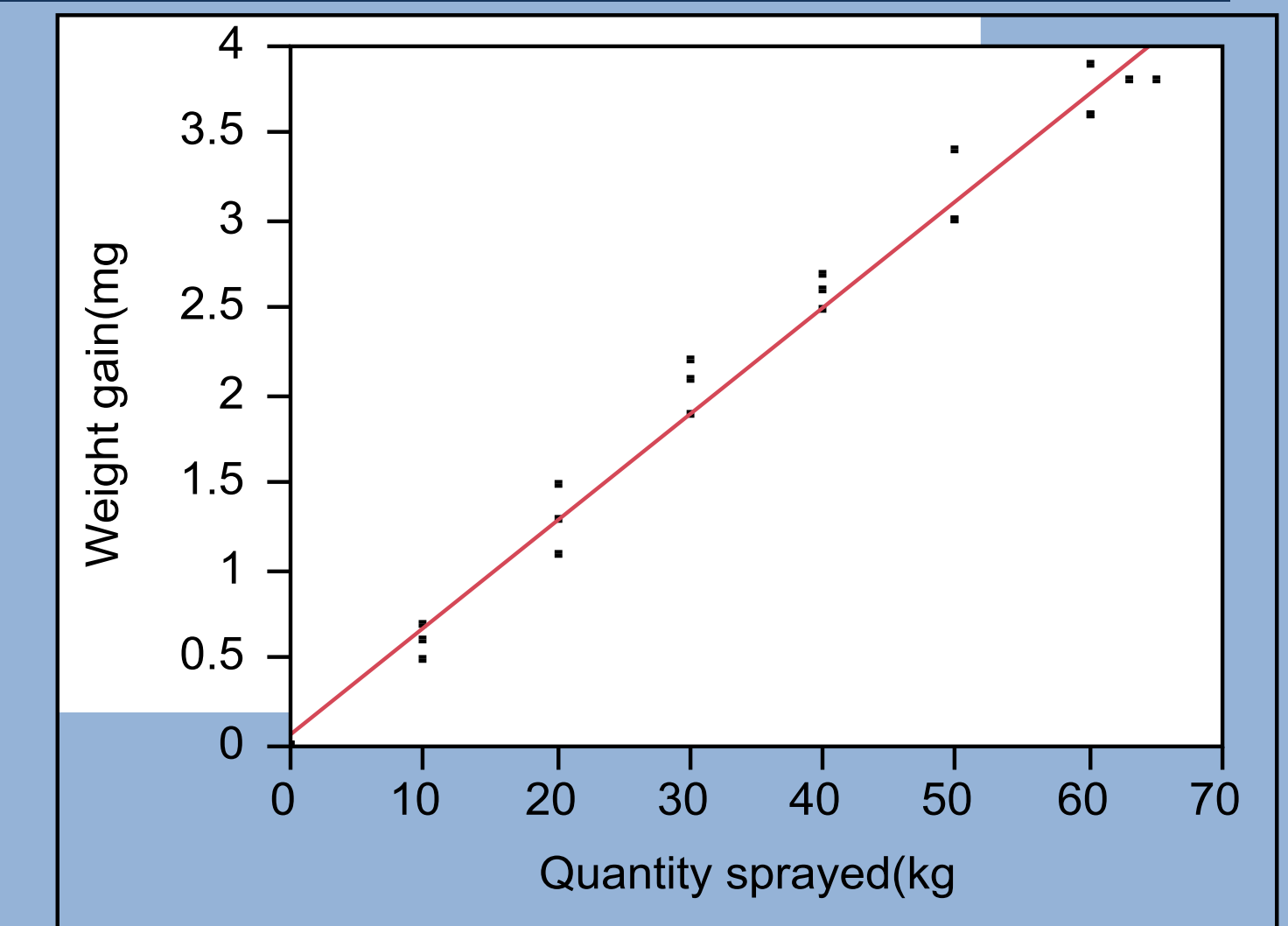
- Opadry Coating System - Colorcon Inc. West Point, PA. (www.colorcon.com)
- Accela Cota Tablet Film coaters Thomas Engineering, Hoffman Estates, IL. (www.thomaseng.com)

Bivariate Fit of Weight gain(mg) By Quantity sprayed(kg)
Linear Fit Weight gain(mg) = 0.0685779 + 0.0609798*Quantity sprayed(kg)

Summary of Fit

RSquare	0.99
RSquare Adj	0.99
Root Mean Square Error	0.16
Mean of Response	2.08
Observations	23

RESULTS



CONCLUSIONS

- When data is displayed as a scatter plot, it is often useful to attempt to represent that data with the equation of a straight line (linear regression) for purposes of predicting values that may not be displayed on the plot.
- For example by using Quantity sprayed vs. Weight gain plot we can predict weight gain of tablets per quantity sprayed of film coating dispersion.
- By linear regression analysis and multivariate process control, we can minimize over drying or wet tablets issue during the film coating operation. Using QbD quality is built into the manufacturing process for tablet film coating.
- From linear regression analysis, it can be seen the R square have of 0.99 indicated that they coating performed was linear and the weight gain (mg) achieved is linearly correlated.
- The coated tablets underwent a visual inspection for acceptable quality levels (AQL) and were deemed acceptable.
- The data generated was confirmed across three batches to achieve repeatable and reproducible results. There by quality is built into the process by achieving uniformly coated tablets during the tablet film coating process.

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- Theory and Practice of Industrial Pharmacy by Lachman L, Lieberman H., Kanig J., 3rd Ed., Lea & Febiger Philadelphia.