DOE Modelling and Optimization of Tablet Coater Mechanism

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Abstract

Tablet coating is one of the Pharmaceutical Process in which coating material is being sprayed on granulated tablets. There are several types of equipment used in order to coat the tablets. Among them the one with perforated pan is quite effective in order to get proper flow of air when there is simultaneous process of spraying wetting and drying. The coating of the tablets in the pharmaceutical industry generally involves many factors but in this DOE modelling three main factors have been considered related to spray arm mechanism This work aimed to development and doe analysis of tablet coater SC700 and optimization using factorial design. The factors consider were: 1. Gun to bed distance (cm) 2. Spray rate (gm/min) 3. Pattern air pressure(bar).
Keywords: Coating, Spray ARM, Gun to Bed Distance, Spray Rate, DOE

I. INTRODUCTION

Tablet coating is the essential process in which coating material is applied as the outer layer on granulated compressed form of tablet. Purpose of tablet coating is to provide taste and odour masking, control drug release rate, provide unique identification to tablet, protect active pharmaceutical ingredient from dust, chemical protection, etc. Predicting Parameters affecting coating process of tablets its quiet difficult and slight variation in the factors may result in poor product quality as tablets may break or get over-wet or chipping and picking of tablets may come into picture.

In order to perform Design of Experiment it is essential to find out factors which play important role in the system and we need to prioritize them. Spray related Parameters are Spray Gun design, No of guns, Spray rate, Gun to bed distance, Atomizing air pressure, Pattern air pressure, Angle of spray gun to tablet bed which affect Droplet size of spray, spray pattern shape and its distribution which then ultimately affect Film quality of final product[3] process engineers should take full advantage of a far simpler tool for DOE – two-level factorials, which can be very effective for screening the vital few factors (including interactions) from the trivial many that have no significant impact.

II. MATERIAL AND METHOD

The Coater is designed to coat tablets. The tablets are loaded into the product pan where they collect in the form of a product bed. The coating of the tablets within the product pan is achieved by means of spraying and dispersing the medium onto the product and then drying with preconditioned air. The rotating movement of the product pan and the mixing baffles prevents the tablets from sticking to each other and provides for a thorough mixture of the product as well as the necessary homogeneous distribution of the suspension. The spray medium is sprayed over the product bed through a spray nozzle. Depending on requirements, this can be done either continuously or through a series of programmed spray cycles. The tablets are dried by the process air that is sucked through the product bed. The discharge system allows a dust- and contamination-free discharge of the product bed. The outlet air fan produces negative pressure in the Coater throughout the process. Optimum product processing conditions can be selected to suit individual product requirements. Following table represents process parameters considered and their operating range for particular application.

Spray pattern determines the number of tablets that get coated during each rotation of pan and each pass through the application zone covered by spray zone. High spray rate may increase the moisture content of the air in the pan and also result in sticking and twinning of the tablets but if the spray rate is very low then spray may get dry before applying on tablets resulting in coating efficiency Patter air Pressure decides the spray pattern shape. Atomizing air pressure and pattern air pressure should be adjusted appropriately to achieve elliptical spray pattern shape which should not overlap to avoid localized over-wetting [2] and provide uniform coating. The gun to bed distance is the distance between the tip of the spray nozzle and imaginary plane on the cascading bed of tablets. Hence, before hitting the tablet surface the distance travelled by the spray droplets is the distance from spray un to tablet bed. Gun to bed distance adjustment is done by operator by his own decision while performing coating operation on tablets by observing coating thickness. Optimum gun to bed distance should be selected as if the gun to bed distance is too high then spray droplets may get dry before reaching to the tablet bed and if the distance is too low then tablets may get over-wetted. An automated mechanism is required to control the movement of spray arm that is to control and adjust the gun to bed distance from outside without stopping the process.

III. EXPERIMENTAL DESIGN

A 2^3 fractional factorial design was prepared to statistically analyse the final product properties mentioned above eight experiments were carried out, which correspond to two levels for the three process parameters.

Table - 1
Process parameters and operating limits range

Parameters	*Range*
Gun to Bed Distance (cm)	*15-30 cm*
Spray Rate (gm/min)	*400-450gm/min*
Pattern Air Pressure (bar)	*1-1.2 bar*

IV. RESULTS AND DISCUSSION

A. *Statistical Analysis:*

The statistical analysis was carried out by design expert software

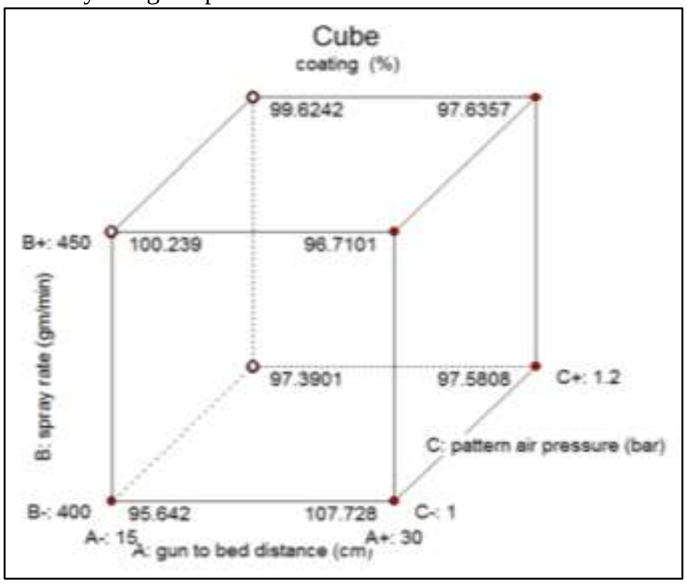

Fig. 1: Cube representing DOE Model

Table – 2
Characterization Results

Run	*Gun to bed Distance (cm)*	*Spray Rate (gm/min)*	*Pattern Air Pressure (bar)*	*Coating Response (%)*
1	*30*	*400*	*1.2*	*97.5808*
2	*30*	*450*	*1*	*96.7101*
3	*15*	*400*	*1.2*	*97.3901*
4	*30*	*450*	*1.2*	*97.6357*
5	*30*	*400*	*1*	*107.728*
6	*15*	*400*	*1*	*95.642*
7	*15*	*450*	*1*	*100.239*
8	*15*	*450*	*1.2*	*99.6242*

Table – 3
Coefficient estimates of factors and their interactions

Factors	*Coefficient Estimates*
Intercept	*99.07*
A	*0.84*
B	*-0.52*
C	*-1.01*
AB	*-2.22*
AC	*-1.29*
BC	*1.09*
ABC	*1.68*

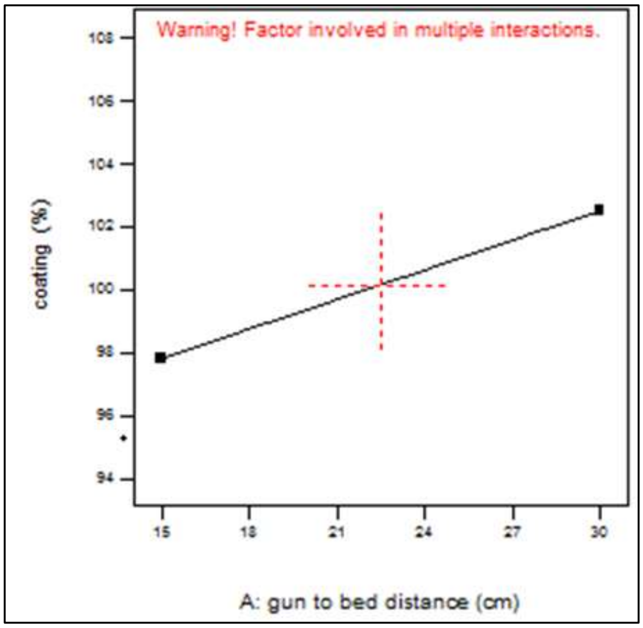

Fig. 2(a)

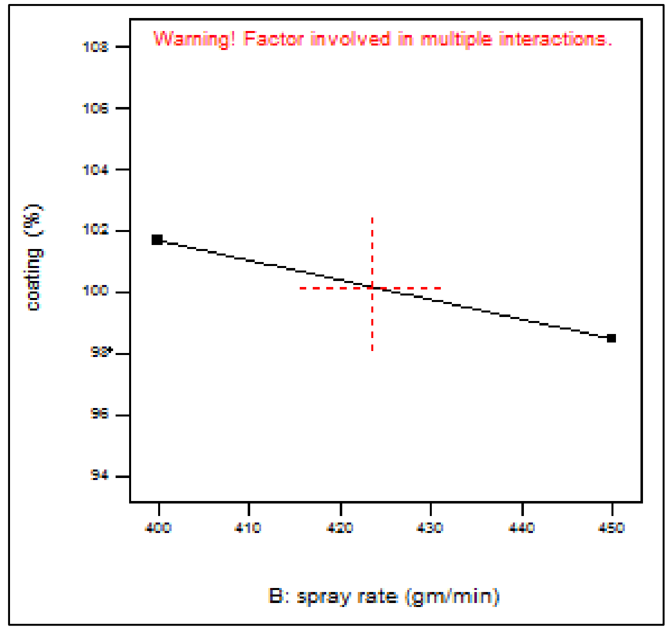

Fig. 2(b)

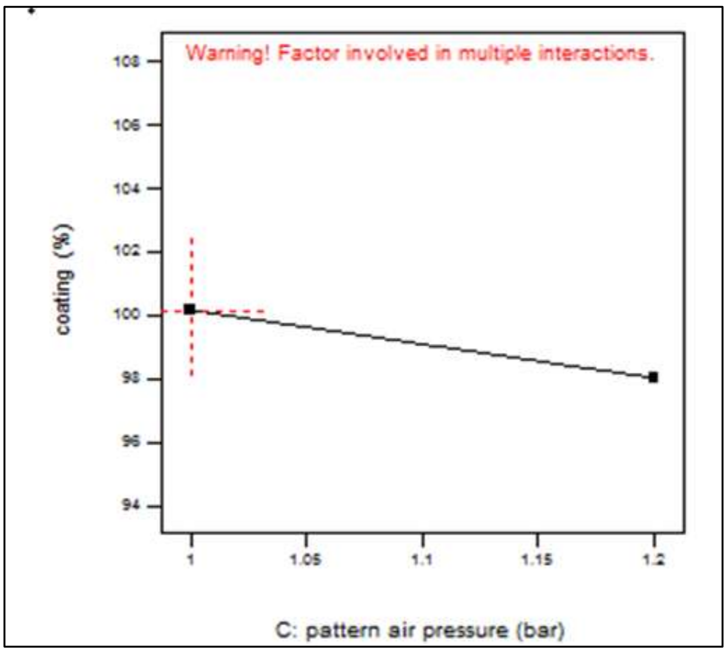

Fig. 2(c)

Fig. 2: (a), (b), (c) Represents Effect of gun to bed distance, spray rate and pattern air pressure on coating

From table 3 mathematical modelling of the system for considered factors can be written as:

$$Response= 99.07+(0.84*A)-(0.52*B)-(1.01*C)-(2.22*AB)-(1.29*AC)+(1.09*BC)+(1.68*ABC)$$

Gun to bed distance has positive effect on the coating but increase in spray rate and pattern air pressure creating negative effect on coating, but optimised interaction of spray rate and pattern air pressure has positive effect on the coating efficiency

B. Perturbation Plot:

The "perturbation" plot shown in Figure3 illustrates this by the straight line for A. This plot originates from the center point of the experimental region and from there it measures response in each of the three dimensional axes.

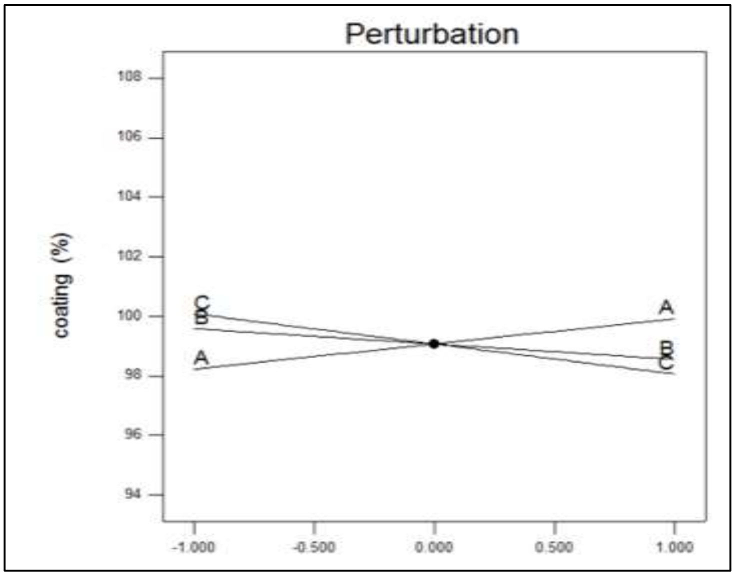

Fig. 3: Perturbation Plot DOE Model

C. *Standard Error Plot and Contour Plot:*

Fig. 4 shows 3D plot of standard error of design. The dots represent the co-ordinates of design points which range from -1 to +1 in coded factor units

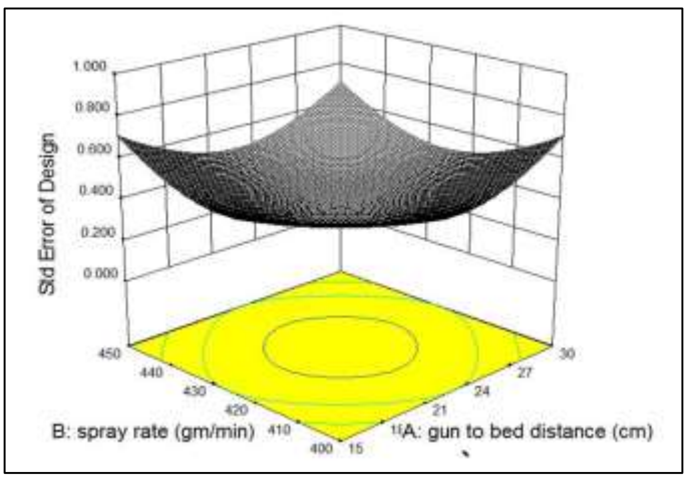

Fig. 4: Standard Error Plot

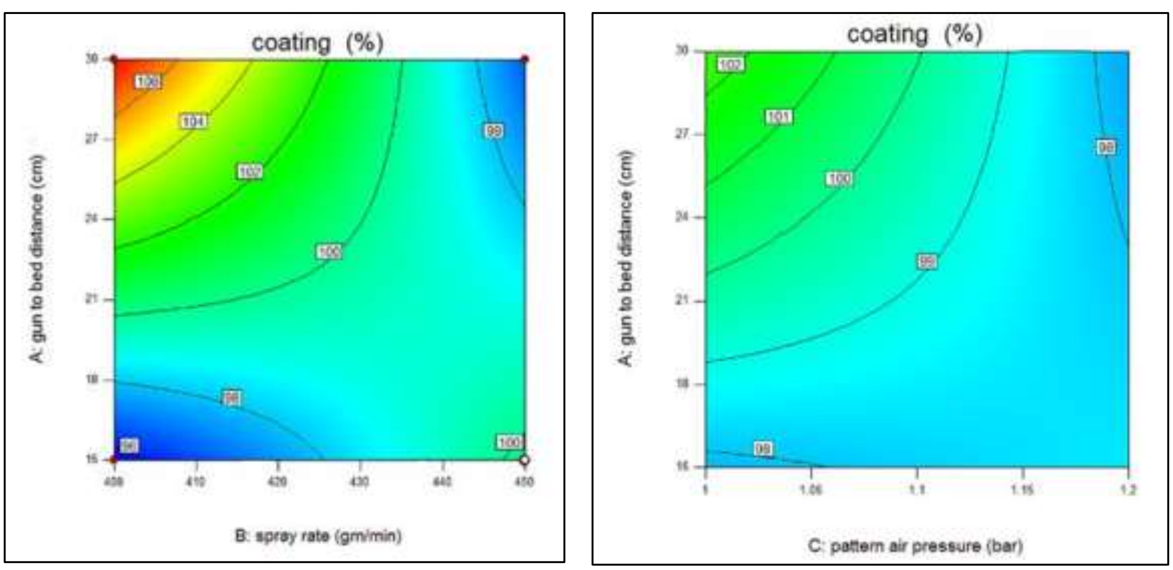

Fig. 5: Contour Plot

D. Optimization:

Optimization of the parameters value in there range is calculated by design expert Insertion of the optimization criteria it possible to obtain the optimal process parameter values for a given set of final product properties. An experiment was carried out using this set of optimal process parameter condition the measured final product properties of the experiments compared with the statistical model prediction.

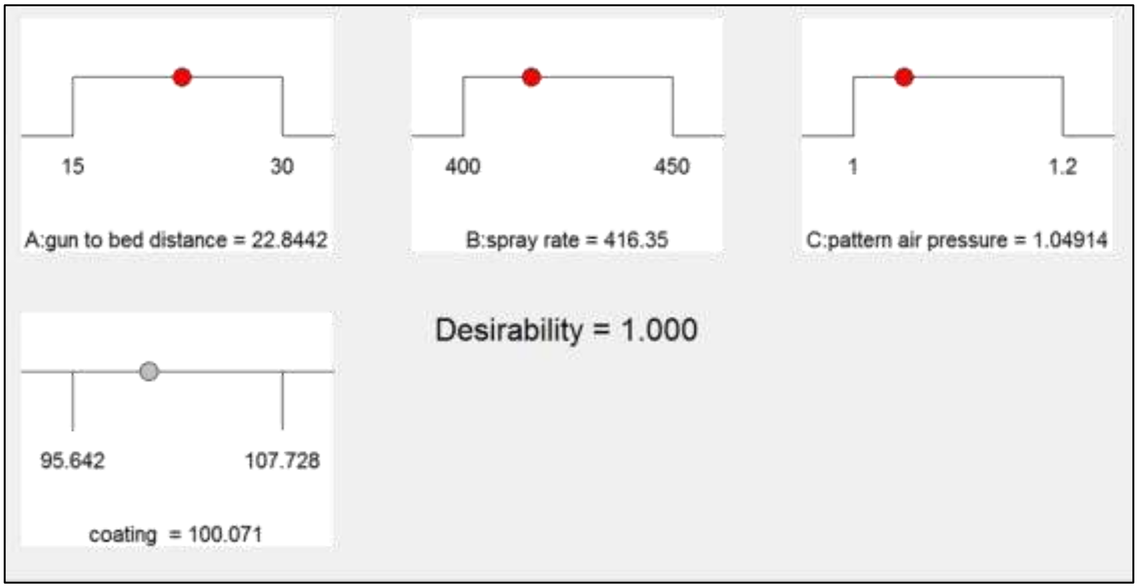

Fig 6: Optimised parameters

V. Conclusion

This work studied the tablet coating process with respect to four process parameters (1) Gun to bed distance, (2) Spray rate, (3) Pattern air pressure. A statistical linear regression model first allowed the determination of an optimized set of operating conditions in order to obtain a high quality final product, The statistical model was experimentally validated, with observed.

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