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Coating Performance Evaluation of Instacoat™ 4G in a Bectochem Lödige Coater

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PURPOSE

The pharmaceutical industry is always keen to improve manufacturing efficiency and product quality by adopting innovative technologies. Coating systems with high solids are used to significantly save both process time and overall energy consumption. The present study evaluates the coating uniformity and appearance of tablets coated with Ideal Cures revolutionary product **INSTACOAT™ 4G** , a high solids aqueous coating system of 35% solids capability, in the Bectochem Lödige Coater.

OBJECTIVE

To evaluate coating uniformity and appearance of **INSTACOAT™ 4G** High Productivity Coating System (35% Solids Capability) using the Bectochem Lödige Coater.

METHOD

- **INSTACOAT™ 4G**, a high productivity film coating system from Ideal Cures, was reconstituted at 35% solids concentration in water and applied at a target weight gain of 3%. The coating dispersion was evaluated for appearance and viscosity.
- Round shaped placebo tablets were used for the coating trials. Coating trials were performed in a Bectochem Lödige Coater using predetermined optimized coating conditions. The specially designed perforated drum of this coater maximizes drying air flow.
- Coating process evaluation was carried out in terms of coating process time, finished tablet appearance, coating defects and disintegration time.
- Coated tablet samples were collected from the top front position of the coating pan at different time intervals (15 minutes) until the completion of the coating process. Color difference of the coated tablets was measured using a reflectance spectrophotometer.

Table No. 1. Core Tablets And Coating Formulation Details

A)Placebo Tablet Details	
Placebo Tablet dimensions	12 mm round Biconvex tablets, plain on both sides.
B) Coating Formulation Details	
Product Name	**INSTACOAT™ 4G**
Color	Yellow
Solids Level (%w/w)	35

Figure No.1. Bectochem Lödige Coater

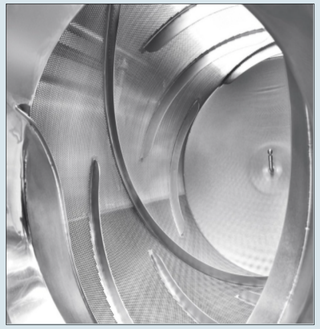

Figure No.2. Internal View of the coating pan

Table No.2. Coating Process Parameters

INSTACOAT™ 4G	**Parameters**
Pan Diameter (inch)	60
Target Weight Gain (%)	3.0
Bed Temperature (°C)	40-45
Atomizing Air Pressure (bar)	3
Gun to Tablet bed distance (cm)	20-22
Pan speed (rpm)	2-7
Spray rate (g/min)	90-100
Actual Spraying Time taken (min)	140

RESULTS

- The coating trial of **INSTACOAT™ 4G** was successfully executed using Bectochem Lödige Coater.
- Results of coated tablet evaluations were found acceptable.

Table No.3. Coating Trial Observations

Parameters	**Observations**
A) Coated Suspension Characteristics	
Appearance	Free-flowing, agglomerate-free yellow coating suspension
Viscosity (cP)	209.4
B) Process Feasibility	
Ease of Operation	No gun blocking observed during the coating process.
Sprayability	Agglomerate free and easily sprayable coating suspension.
C) Coated Tablet Characteristics*	
Appearance*	Smooth
Colour Difference (dE)	1.25
Disintegration Time (Sec.)**	60
Coating Defects*	Nil

*100 tablets were observed for Appearance and Coating Defects.
**Disintegration Time of Uncoated Tablets: 34 seconds.

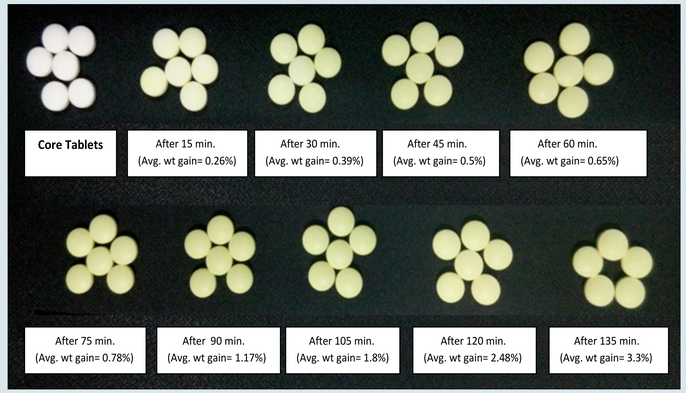

Figure No. 3: Coated tablets at different coating process time points

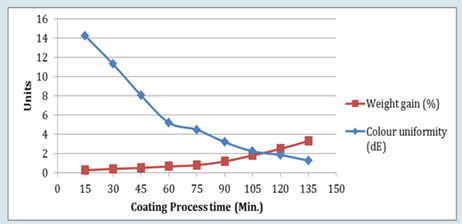

Figure No. 4: Graphical representation of weight gain and color uniformity at different coating process time points

CONCLUSION

The **INSTACOAT™ 4G** coating formulation was successfully applied using Bectochem Lödige Coater. Good color uniformity and surface finish was achieved even at high solids (35%) level of **INSTACOAT™ 4G** within a short coating process time.

FUNDING / GRANTS / ENCORE / REFERENCE OR OTHER USE

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IDEAL CURES INSTACOAT 4G