Ideal Cures Pvt. Ltd.

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Evaluation of Instacoat 4G™ High Productivity Coating System (35% Solids Capability) Using the O'Hara Technologies Continuous Coater

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PURPOSE

The pharmaceutical industry has always been focusing on improving manufacturing efficiency and product quality with adoption of innovative technology. In view of these trends, the concept of continuous coating technology that improves efficiency and increases productivity has been introduced. High solids coating systems are used to achieve significant savings in 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 ,** high solids aqueous coating system of 35% solids capability using O'Hara Technologies Inc.'s Continuous Tablet Coater (CTC).

OBJECTIVE

To evaluate coating uniformity and appearance of **INSTACOAT™ 4G,** High Productivity Coating System (35% Solids Capability) using the O'Hara Technologies Continuous Coater

METHODS

The coating system used was **INSTACOAT™ 4G** , a high productivity film coating system reconstituted in water at 35% solids concentration and applied at a target weight gain of 2.5%.

Table No. 1. Core Tablets And Coating Formulation Details

A)Placebo Tablet Details		
Placebo Tablet dimensions	19.5 x 9.3 x 5.5 mm oblong shaped tablets having the INSTACOAT Logo on both faces.	
B) Coating Formulation Details		
Product Name	**INSTACOAT™ 4G**	
Color	Brown	Yellow
Solids Level (%w/w)	35	

Coating Trial Details

Two trials were conducted in an O'Hara Fastcoat, Continuous Tablet Coater (Model: FC C500) fully perforated pan (Figure No. 1), equipped with 14 spray guns (Schlick Gun) at SAG Manufacturing, Madrid (Spain). Tablets were fed continuously onto a weigh belt from an over bulk hopper after the completion of initial coating in batch mode. After moving through the spray zone where the desired amount of coating was applied, tablets were then discharged. During the feeding of fresh tablets, zones 1 and 2 were filled with uncoated tablets, which were coated subsequently as they moved towards the discharge zone. The resident load in the coater was approximately 430 kg during the continuous coating process. The process was controlled to maintain coating temperatures and other conditions similar to those used in a typical (non-continuous) batch coater. Once the entire batch was completed, the tablet feed was stopped and exit and inlet gates closed. Coated tablets were discharged from the other side of the coating pan after achieving the desired 2.5% average weight gain.

Figure No.1. Continuous Coating Pan (O'Hara Technologies Inc.)

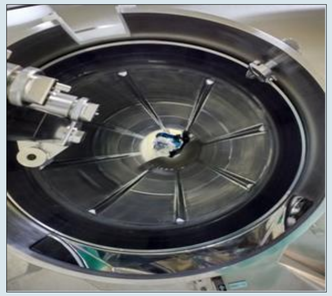

Figure No. 2: Internal View of Continuous Coating Pan

Tablets were evaluated for appearance, colour uniformity; tablet to tablet weight variation and disintegration time. Colour uniformity of the coated tablets was measured using a reflectance spectrophotometer.

Table No. 2. Coating Process Parameters

INSTACOAT™ 4G	**Brown**	**Yellow**
Pan Diameter (inch)	48	
Target Weight Gain (%)	2.0	
Bed Temperature (°C)	43-45	43-46
Atomizing Air Pressure (bar)	3	
Pattern Air Pressure (bar)	3	
Drum speed (rpm)	10-20	10-24
Airflow (cfm)	9500-10000	9500-10000
Solution Flow Rate (g/min.)	460-480	465-485

RESULTS

- The coating trial of **INSTACOAT™ 4G** was successfully executed using a O'Hara Engineering Continuous Coater.
- Results of coated tablet evaluations were found acceptable.

Table No.3. Coating Trial Observations

Parameters	**Observations**	
	Brown	**Yellow**
A) Coated Suspension Characteristics		
Appearance	Free-flowing, agglomerate-free coating suspension	
Color	Brown	Yellow
Viscosity (cP)	109.8	201.6
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	
Logo Clarity*	Excellent Logo Clarity	
Colour Difference (dE)	0.39	0.58
Disintegration Time (Sec.)	46	48
Coating Defects	Nil	
Adhesion (gf)	1805.9	1774.1
Tensile Strength (MPa)	1.0699	1.2497

***100 tablets were observed for Appearance, Logo Clarity and Coating Defects.**

Figure No. 3: Tablets coated with INSTACOAT™ 4G

CONCLUSION

The **INSTACOAT™ 4G** coating formulation achieved high tablet throughput rate (500 kg tablets/hour) in continuous mode of coating operation. Good color uniformity and surface finish was achieved even at high solids (35%) level of **INSTACOAT™ 4G** .

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IDEAL CURES INSTACOAT 4G