Pea starch as an environmentally sustainable solution in pharmaceutical film coating applications using the ReadiLYCOAT® system

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PURPOSE

This study evaluates the sustainability and performance advantages of a naturally sourced hydroxypropyl pea starch-based film coating system (ReadiLYCOAT® [RL], Roquette), compared to conventional film polymer coatings in pharmaceutical manufacturing. RL is compared to Tabshield® H semi-synthetic HPMC-based coating system (Roquette) and Tabshield® P synthetic PVA-based coating system (Roquette). The research investigates sustainability attributes and manufacturing performance, focusing on energy consumption during the coating process of temperature-sensitive drug products at product bed temperatures below 35°C, contrasted with HPMC- and PVA-based polymers requiring higher bed temperatures. Additionally, the study assesses the efficiency of equipment cleaning procedures. By quantifying these factors under industrial-scale conditions, this research provides a comprehensive evaluation of RL's potential to enhance ecological and operational outcomes in pharmaceutical film coating applications.

OBJECTIVE(S)

To verify the sustainability and performance advantages of a new generation immediate-release film coating with naturally sourced pea starch-based film polymer (ReadiLYCOAT® (RL), Roquette), compared to conventional synthetic (PVA-based) and semi-synthetic (HPMC-based) film polymer coatings at the level of simulated commercial-scale pharmaceutical manufacturing.

METHOD(S)

Industrial-scale trials were conducted using a FREUND model HC-60M HI-COATER® system with a 240-liter perforated coating pan. Each trial processed 142 kg of placebo tablets (9.55 mm diameter, 5.5 mm thickness, 408 mg weight) of starting pan load. Coating suspensions were prepared with 20% w/w solids for RL and PVA, and 15% w/w solids for HPMC. The coating suspension was applied using a FREUND AT manifold gun bar equipped with four guns, each with 1.2 mm fluid tips and 015 air caps. Process parameters were controlled to maintain product bed temperatures within the optimal film-forming range for each polymer. Relative Average Energy Factors (RAEF) for each coating process during the spray cycle were computed with the following equation:
[(Inlet Airflow) × (Inlet Air Temperature – Dehumidified or Chilled Air Temperature)]. RAEFs were normalized (NEF) by dividing the average energy factor by the water spray rate (spray rate × % water in formulation) to account for formulation water content variations. Comparative efficiency was determined by calculating the percentage energy reduction achieved by RL relative to HPMC and PVA.
A comparative cleaning efficiency study was conducted. The cleaning study assessed RL Blue (containing Brilliant Blue Lake and titanium dioxide pigments) and HPMC White (containing titanium dioxide). To simulate soiling, 0.40 kg of dried coating solids were applied inside the 240-liter coating pan, equivalent to 2.0 kg of 20% w/w RL Blue suspension and 2.7 kg of 15% w/w HPMC-White suspension. Cleaning was performed without detergents using ambient temperature deionized water delivered through an EcoClean™ 7-nozzle WIP/CIP bar integrated to the spray gun bar. Each cycle dispensed 25 liters of water over a 1-minute duration. Up to eight wash cycles were performed per trial. Visual inspection estimated the percentage of adhered coating residue removed after each wash cycle. Key performance indicators included total wash time, number of cycles to achieve full cleaning, and total water consumption.

RESULT(S)

BATCH COATING PROCESS

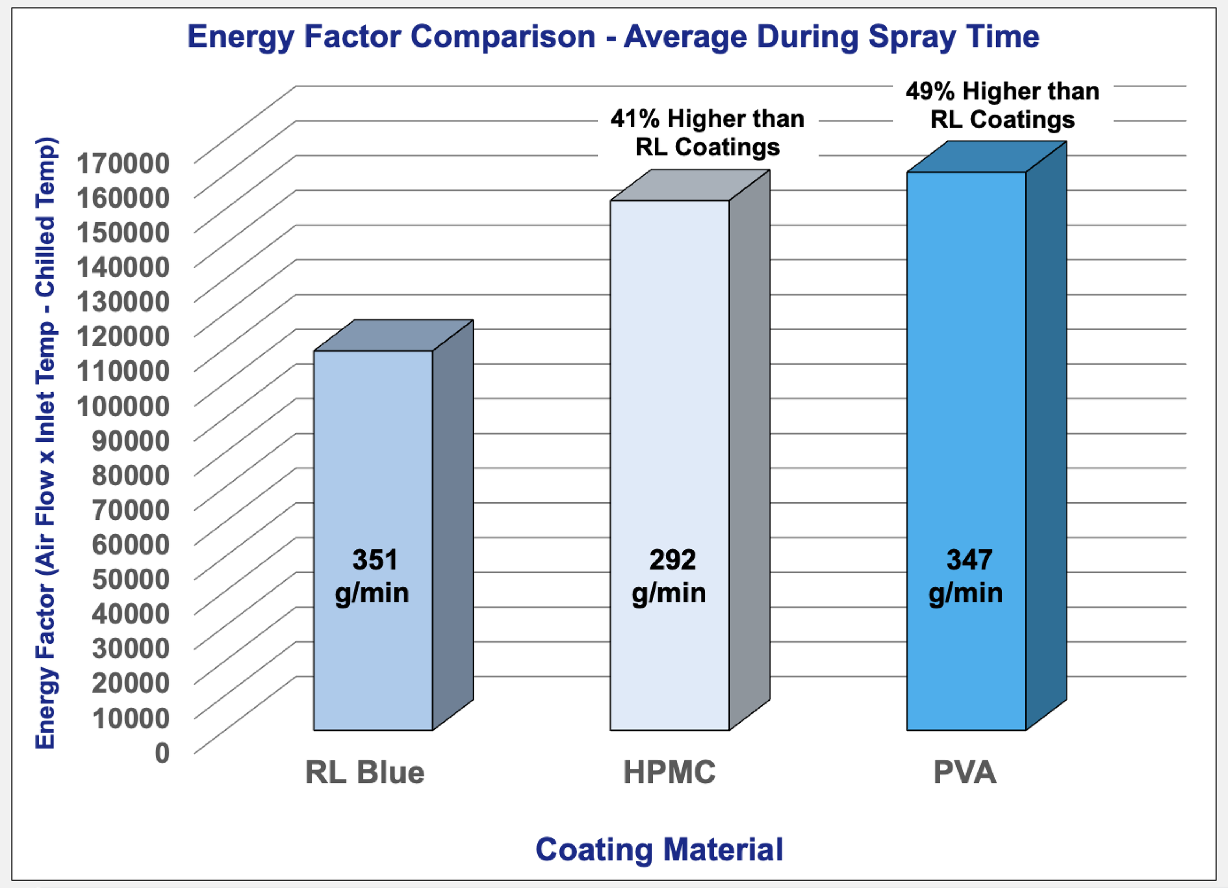
1. AEF, NEF, and coating efficiencies for each of the coating formulations tested are shown in Table 1. RL significantly outperformed HPMC and PVA in energy efficiency during the coating process.
2. HPMC had 41% and 47% relatively higher factors than RL coatings for average and normalized energy factors, respectively. Refer to Table 2.
3. PVA had 47% and 38% relatively higher factors than RL coatings for average and normalized energy factors, respectively. All coating processes had efficiencies ranging from 88% for HPMC to 94% for the plant, modified starch, based RL Blue. Refer to Table 2.
4. Additionally, RL supported higher spray rates, indicating faster and more efficient application without compromising the quality of finished coated tablets.

Table 1. Coating Process Parameters for ReadiLYCOAT®, HPMC, and PVA Coating.

Parameter	Units	Trial A	Trial B	Trial C
Coating Film-forming Polymer		**ReadiLYCOAT®**	**HPMC**	**PVA**
Coating Color		Blue	White	Blue
Coating Solids	%	20	15	20
Dehumidified or Chilled Air Temperature	°C	8.4	8.4	8.4
Inlet Air Temperature	°C	51.3	68.3	71.7
Product Bed Temperature	°C	30.4	45.3	45.6
Inlet Airflow	m^3/h	2544	2545	2540
Spray Rate, Total	g/min	351	292	347
Spray Time	min	65.5	102.6	66.2
Spray Amount	kg	23.0	30.0	23.0
Atomization Air per Gun	MPa	0.2068	0.2068	0.2068
Pattern Air per Gun	MPa	0.1379	0.1379	0.1379
Spray Gun to Tablet Bed	cm	22-23	22-23	22-23
Pan Speed	RPM	7	7	7
Target Final Coating Weight gain	%	4	4	4

Table 2. Energy Factors and Efficiencies for ReadiLYCOAT® HPMC and PVA Coating.

Parameter	Units	Trial A	Trial B	Trial C
Coating Film-forming Polymer		**ReadiLYCOAT®**	**HPMC**	**PVA**
Average Energy Factor	m3/h*Δ°C	109273	152563	160726
Normalized Energy Factor	m3/h*Δ°C	6.48	10.23	9.65
Coating Efficiency by Weight	%	93.7	87.8	89.3



Graph-1; Energy Factor comparison between ReadiLYCOAT® vs HPMC Vs PVA film coating materials

Fig. 1: FREUND HC-60M HI-COATER® 240L perforated coating pan

Fig. 2: EcoClean™ Wash Skid

EQUIPMENT CLEANING AFTER COATING PROCESS

1. In the cleaning study (see Table 3), RL demonstrated superior performance in speed and water efficiency.
2. Complete RL residue removal was achieved after six cycles (175 liters, 7 minutes), while HPMC required eight cycles (275 liters, 11minutes) for full cleaning. RL reduced cleaning time by 40% and water usage by 45% compared to HPMC.
3. These improvements are attributed to RL's lower viscosity and better rehydration characteristics, facilitating faster and complete residue removal without mechanical scrubbing. In contrast, HPMC's higher viscosity and stronger film adhesion contributed to longer cleaning duration and increased water demand.

Table 3. Equiment Cleaning after Coating Process.

Parameter	Units	Trial A	Trial B
Coating Film-forming Polymer		**ReadiLYCOAT®**	**HPMC**
Number of Wash Cycles	#	6	8
Quantity of Water*	(Liters, kg)	175	275
Cleaning Time	(minutes)	7	11

*25 Liters per minute per each wash cycle

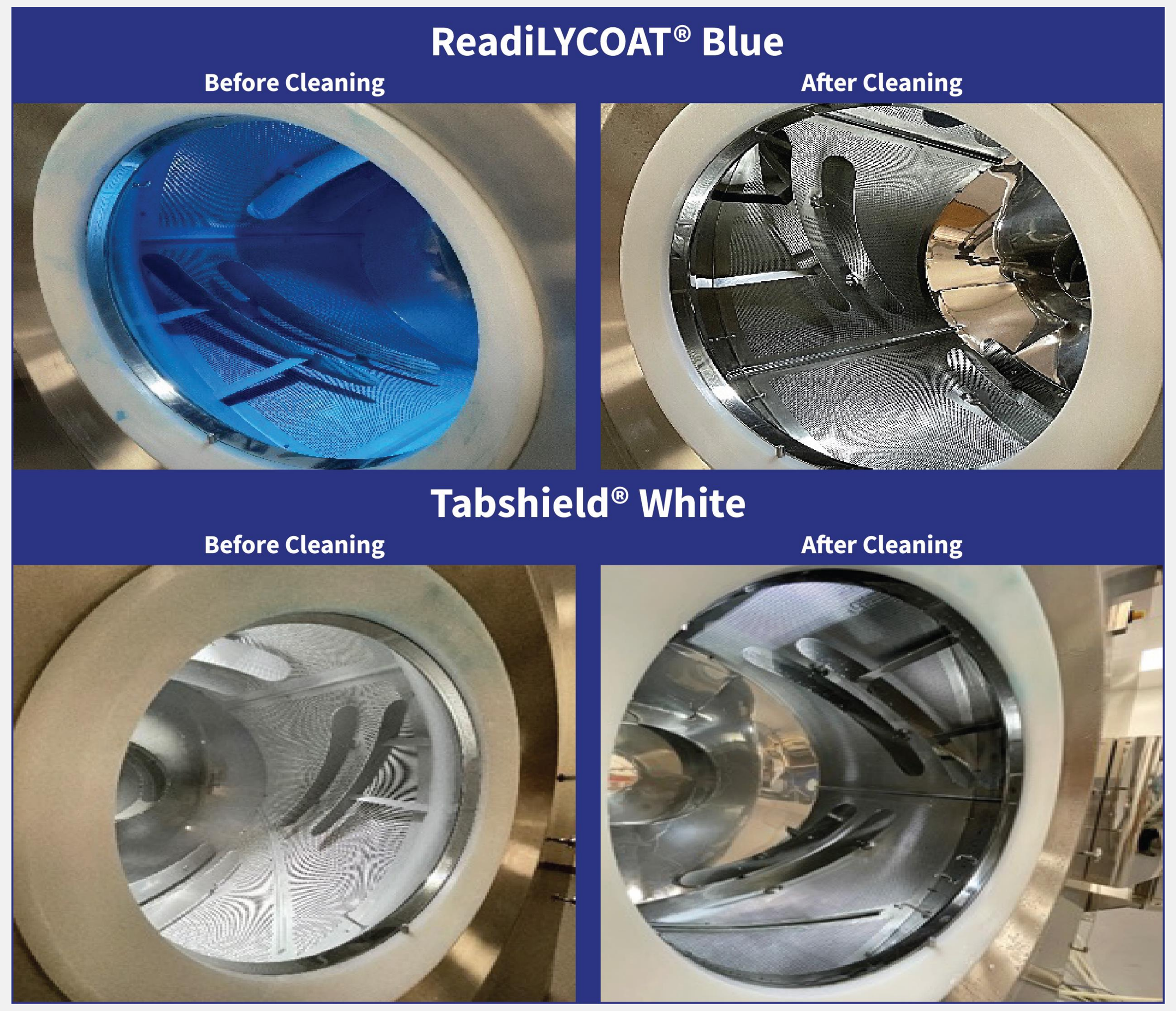


Fig. 3: Images of coating pan before and after cleaning

CONCLUSION(S)

1. RL emerges as a high-performance, sustainable alternative to conventional film coating polymers, offering environmental and cost-saving benefits in pharmaceutical manufacturing environments sensitive to energy constraints.
2. Unlike synthetic polymers such as PVA, derived from petrochemical sources with greater environmental burdens, RL supports greener manufacturing practices without compromising functionality. Its superior cleanability is achieved with less water and time without chemical detergents, enhancing process efficiency and resource conservation.
3. These combined benefits position ReadiLYCOAT® as an ideal solution for pharmaceutical manufacturers seeking to balance performance, productivity, and sustainability in their coating operations for oral solid dosage forms.
4. Pea starch, a renewable and biodegradable raw material, offers environmental advantages, including a lower agricultural carbon footprint, adaptability to varying climate conditions, and reduced energy requirements during film coating processes.

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