

Evaluation of a Novel, High Solids, Film-Coating System for Heat Sensitive Products

Timothy J. Smith¹, Carmen Popescu², Ryan Crawford¹, Gregory Le-Bihan³,
Sebastien Croquet³

¹Freund-Vector Corporation, USA; ²Roquette America, USA; ³Roquette Freres, France



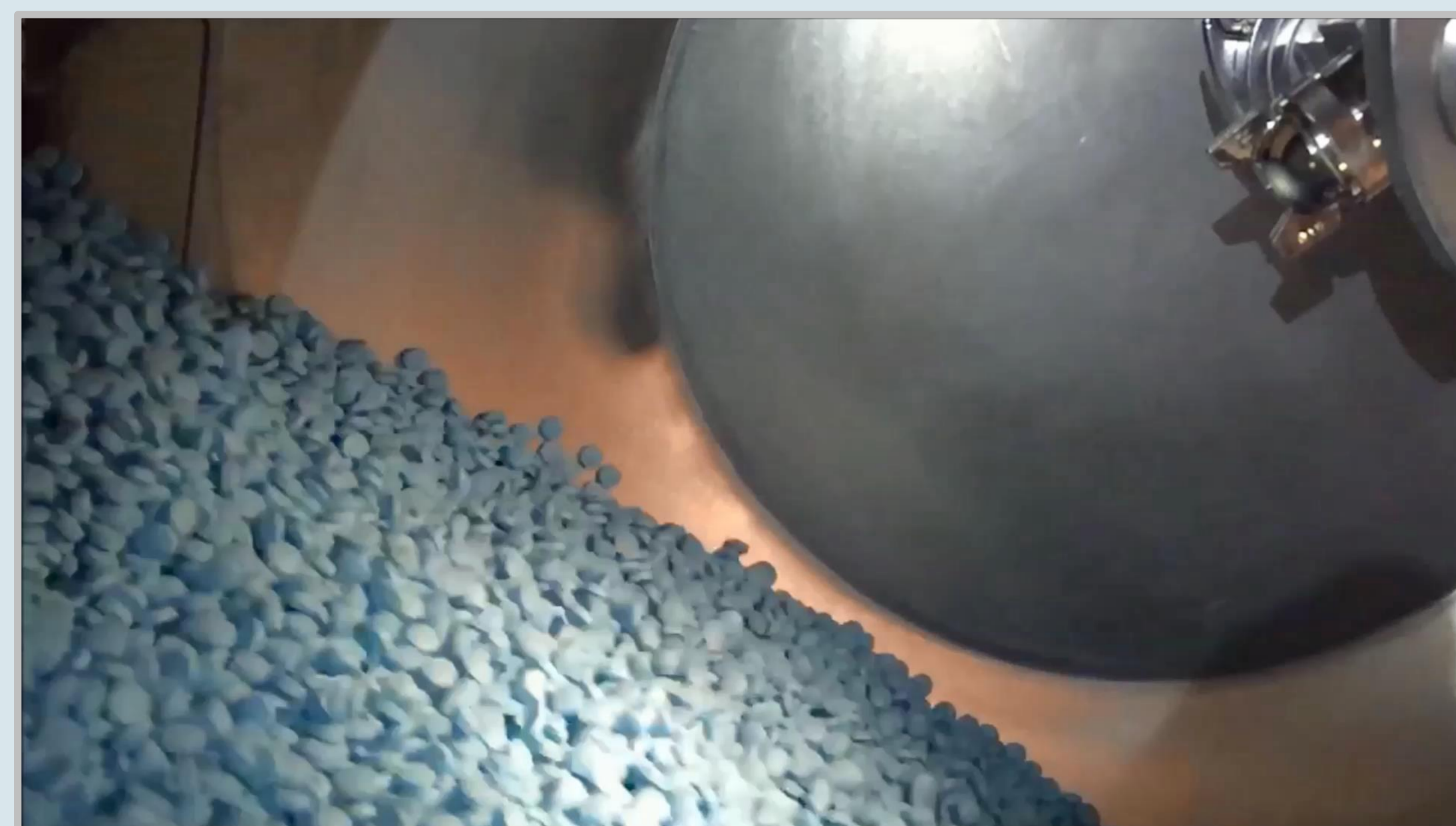
CONTACT INFORMATION: Timothy J. Smith (tim.smith@freund-vector.com); Carmen Popescu (carmen.popescu@roquette.com)

PURPOSE

Processing heat sensitive products below body temperatures with aqueous based coating solutions is challenging. HPMC or PVA based coating formulations typically require film forming temperatures above 40°C. The goal of this study was to evaluate the coating quality of a modified, starch based polymer utilizing various solids percentages at process bed temperatures lower than 35°C for different tablet compositions and batch loads.

METHODS

The core tablets used were 500 mg, oval or 350 mg, round. Tablets were composed of mannitol and magnesium stearate. The coating solution was aqueous based with 20% or 30% solids concentration (ReadiLYCOAT, Roquette). Batch sizes of 30 kg and 55 kg were processed to a 4% by weight coating in a fully perforated 55 or 110 liter coating pan (VHC-5811, Freund-Vector). The coating solution was applied with an AT manifold gun body equipped with a 1.2mm fluid tip and 015 air cap. Process parameters were controlled to achieve product bed temperatures in the range of 33-34 C (table 1). A previously coated tablet (lactose, microcrystalline cellulose, and magnesium stearate) using 20% solids coating formulation was used as a reference standard. Color uniformity was evaluated via spectrophotometric ΔE values (ΔE is a positive number expressing a difference between two colors) using a Konica Minolta CM-5 spectrophotometer. Surface appearance and roughness (ra value) was assessed with a high resolution digital microscope (Keyence VHX-6000).

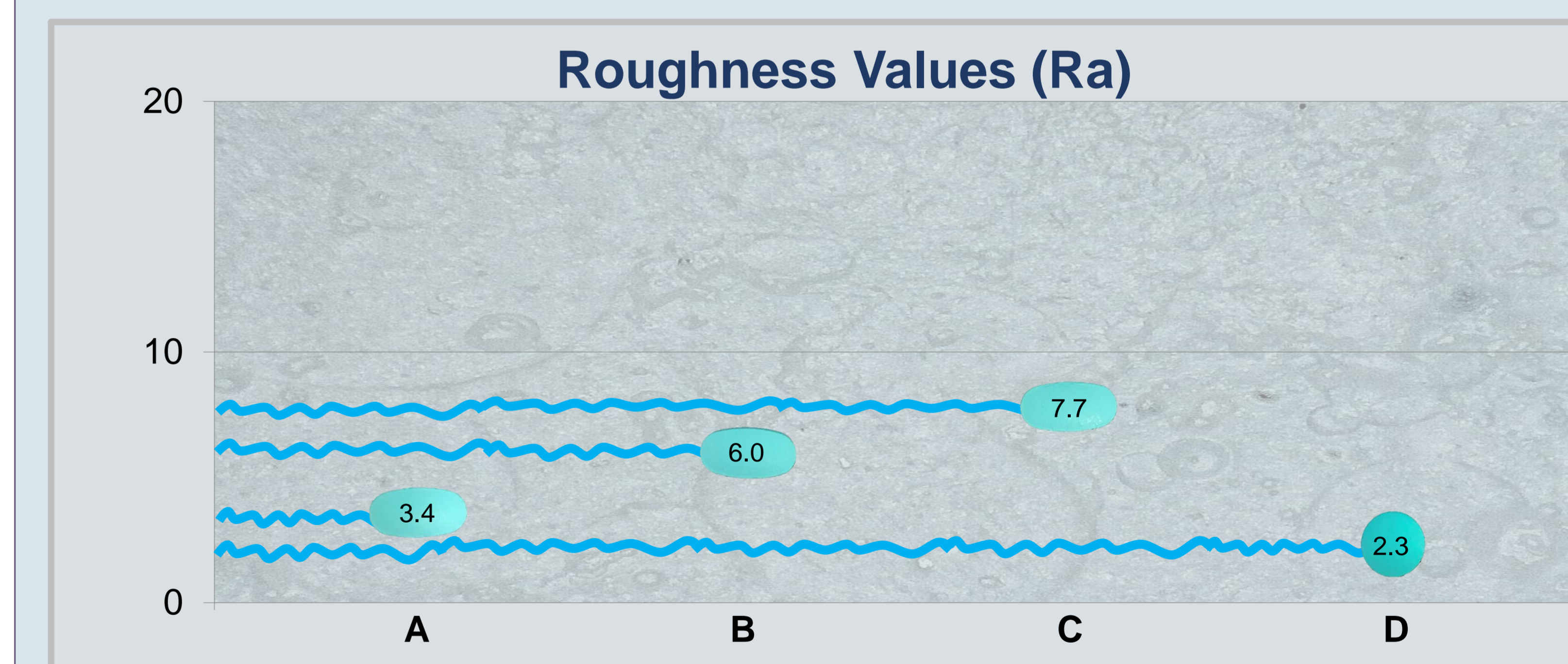
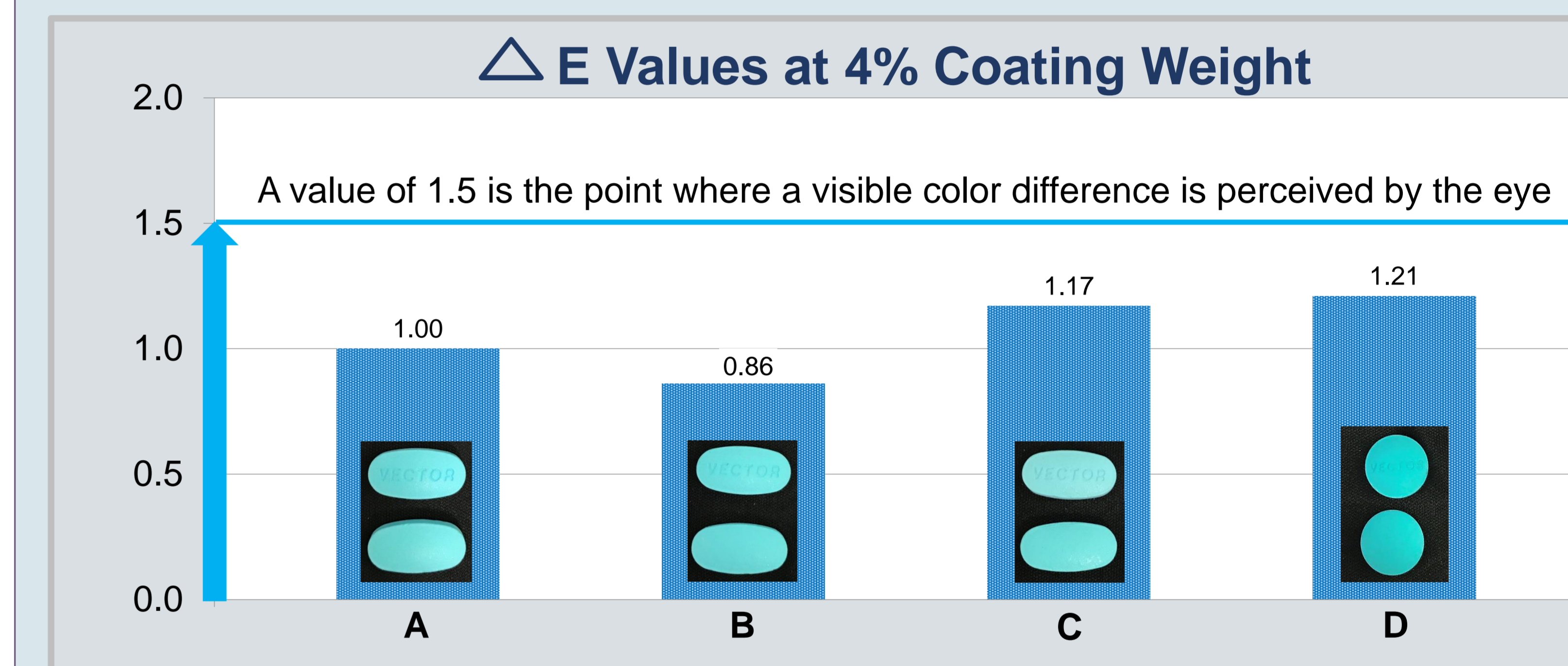


METHODS

Table 1. Process Parameters

Parameter	Trial A	Trial B	Trial C	Trial D
Tablet Size Shape	500 mg Oval	500 mg Oval	500 mg Oval	350 mg Round
Coating Solids (%)	20	30	30	20
Product Bed Temperature (C)	33-34	33-34	33-34	33-34
Inlet Air Temperature (C)	50	44	55	62
Inlet Air Flow (M3/H)	765	765	1020	765
Spray Rate (g/min)	81	61	158	153
Atomization Air (SLPM)	100	100	130	110
Pattern Air (SLPM)	130	130	150	110
Spray Gun to Tablet Bed (cm)	22	17	22	25
Final Coating %	4.0	4.0	4.0	4.0
Spray Time (min)	77	68	49	76
Pan Speed (rpm)	8	8	8	10
Batch Size (Kg)	30	30	55	55

RESULTS



CONCLUSIONS

The novel coating system based on a modified starch polymer shows to be a practical coating solution utilizing high coating solids for coating different core substrate tablets with different batch loads at low bed temperatures (<35°C). It produces a uniform coating while using standard film-coating equipment and only water as a solvent.