

PURPOSE

The pharmaceutical industry is keenly investigating various technologies to prevent counterfeiting of its products. One approach that manufacturers may evaluate is to add trace amounts of inactive ingredients i.e. physico-chemical identifiers (PCIDs) to an existing dosage form which can be detected, thus making it possible to differentiate legitimate and counterfeit products¹. An alternative approach is the use of embedded micro-tags which are very difficult to copy and compared with PCIDs enable the capture of far more information about the product than simply its identity. TruTag Technologies manufactures micro-tags and has experience with incorporation into dry powder film coating systems². The purpose of this collaborative study between IDEAL CURES and TruTag was to formulate a range of INSTACOAT™ clear-coat systems providing simple and economic application of micro-tags in a final 'polish' coat.

OBJECTIVE

The main objective was to provide maximum readable tag density with minimal tag loading while maintaining superior processing capabilities.

METHOD

Four different blends of INSTACOAT™ (Formulation A: HPMC-PEG base and Formulation B: HPMC-Triacetin base) with TruTags having different lot numbers were prepared. These four blends were separately reconstituted in water at 8% solids concentration. The suspensions were evaluated for appearance, pH and viscosity. White and Orange colored tablets were coated. Coating trials were performed in a conventional coating pan with pre-determined coating parameters until a 2% weight gain was achieved. The product bed temperature was maintained at 40°C – 42°C. Sampling was carried out at 1% and 2% weight gain levels.

RESULTS

Table No. 1: Coating Suspension Characteristics

Parameters	Observations			
Formulations	HPMC-PEG-36	HPMC-PEG-37	HPMC-Triacetin-36	HPMC-Triacetin-37
Appearance	Free-flowing, lump free coating suspension			
Color	Transparent			
pH	4.5	4.7	4.4	4.5
Viscosity (cP)	66.9	79.2	67.2	60.0

Coated Tablet Characteristics:

Coated tablets samples were collected at 1% and 2% weight gain. Tablets were visually evaluated for appearance, disintegration time and coating defects. Further samples and their corresponding powder blends were also sent to TruTag Technologies, Inc. for analysis of tag density.

Table No.2: Coated Tablet Characteristics

Parameters	Weight Gain (%)	Quantity of tablets	Observations							
			White tablets (Trial No.)				Orange colored tablets (Trial No.)			
			1	2	3	4	5	6	7	8
Appearance	1 2	20	Smooth and glossy				Smooth and glossy			
Disintegration Time (min.)*	1 2	12	4.55	4	3.53	3.55	4.49	4.30	5	5
			5.54	5.8	5.48	5.2	5.38	5.42	5.52	6.4

*Disintegration time of uncoated tablets was 3 min. 40 sec.

Figures 1 and 2 show the average tag densities observed for all 1% and 2% weight gain batches. For each batch, 20 tablets were read. The tag density ranges are denoted in the below histograms.

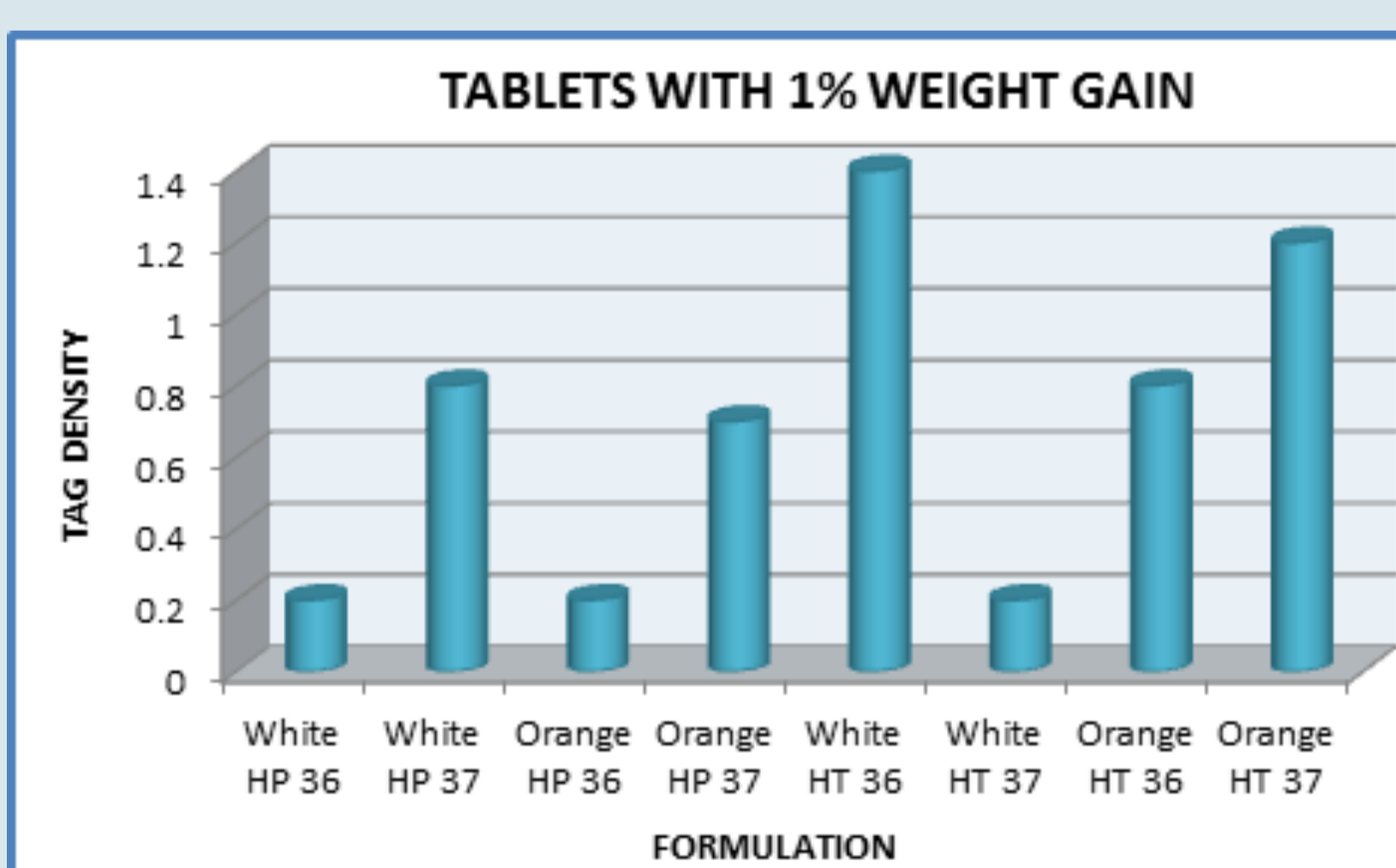


Figure No. 1: Observed tag densities for 1% weight gain samples.

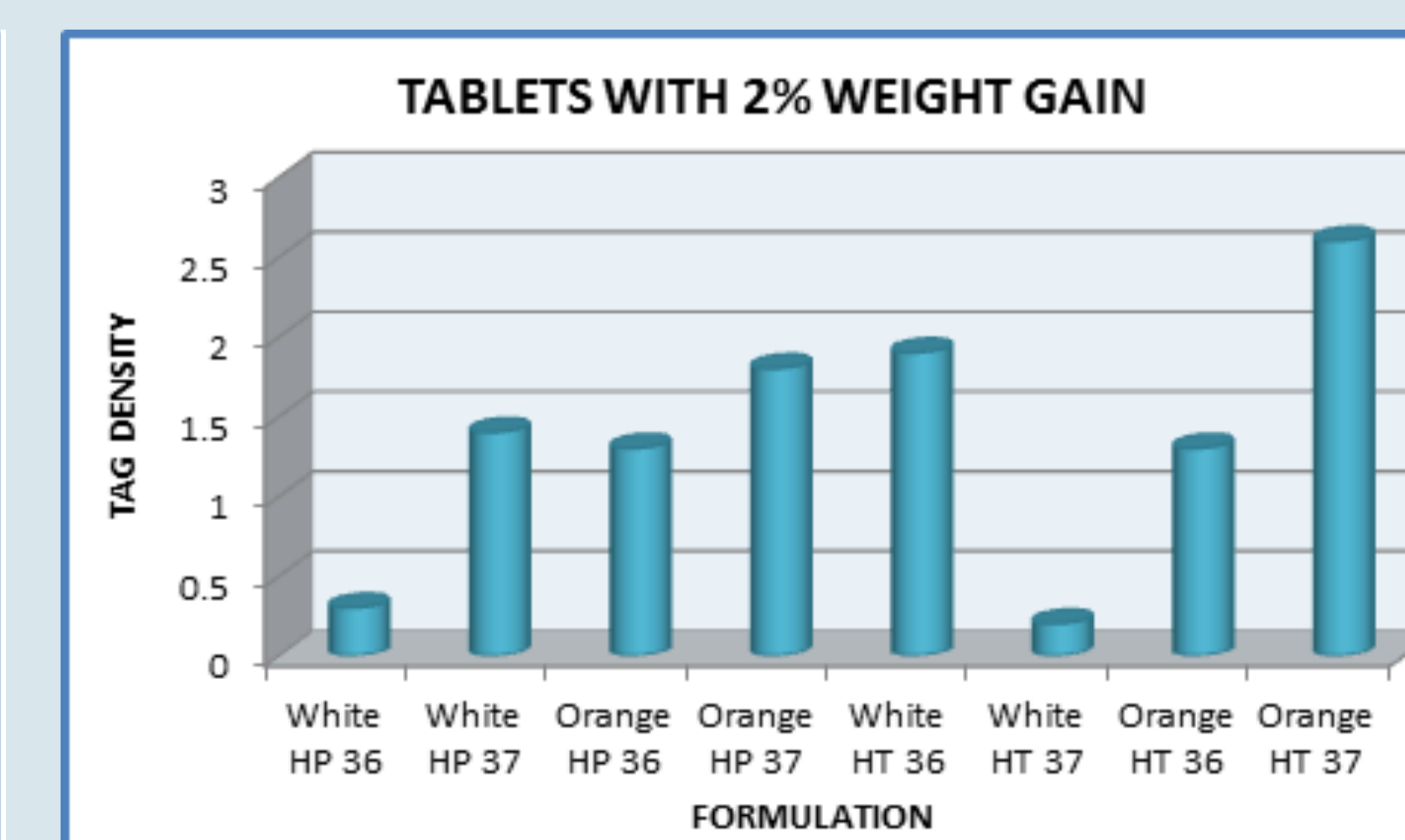


Figure No. 2: Observed tag densities for 2% weight gain samples.

CONCLUSIONS

TruTags were successfully blended homogeneously with Instacoat formulations and coated onto tablets by Ideal Cures. The TruTag authentication time was less than 1 minute, ranging from 19 seconds for the highest density to 55 seconds for the lowest density. The integrity and physicochemical characteristics of Instacoat formulations are maintained even after the addition of the microtags.

REFERENCES

- Guidance for Industry-Incorporation of Physical Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anti-counterfeiting. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), October 2011, CMC.
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IDEAL CURES

INSTACOAT 4G