Soteria Rx®
Protect | Secure | Smart

Colorcon®

Delivering Smarter Medicines with On-Dose Microtaggants and Smartphone Technology

Authors: Ahsanul Howlader, George Reyes, Manish Ghimire, Daniel To, Ali Rajabi-Siahboomi

Colorcon, Inc. Harleysville, PA 19438, USA | AAPS Poster Reprint 2022

Introduction

Drug counterfeiting and diversion is an escalating problem due to low risks and high potential rewards for criminals.[1] The most significant impact on the continued growth of counterfeit drugs is the increased availability of fake products through e-commerce, especially illegal online channels.[2] In addition, medicines are often separated and repackaged from the original, making serialization and track and trace solutions no longer effective. On-dose authentication provides an additional layer of protection directly on the dosage form that can easily be verified.[3] This innovative technology, where a microtaggant is added to a tablet as part of the film coating, enables health professionals and patients to verify their medicine directly using a smartphone. These smart medicines can be scaled to provide real-time data collection and analysis that will improve patient engagement, reduce medication errors, and identify fake or diverted drugs.

One of the SoteriaRx® on-dose authentication solutions uses silica-based taggants made from silica dioxide, a common excipient used in pharmaceutical formulations. These microtaggants are microscopic particles that are virtually invisible to the naked eye and have been engineered to reflect a unique spectral fingerprint that can be confirmed through a smartphone app. In this study, the microtaggants were added to Opadry® complete film coating systems (clear and white pigmented) and applied to placebo tablets. The tablets were then evaluated for authenticity and performance attributes investigated during storage at ambient and accelerated conditions.

Methods

Opadry samples (clear and pigmented) with and without the inclusion of silica-based microtaggants were coated, using a Labcoat I fitted with a 12” fully perforated coating pan (O’Hara Technologies, Inc.), onto 360 mg placebo tablets using identical coating conditions, described in Table 1. The clear coating was applied to 1% weight gain (WG) to achieve uniformity, and the pigmented coating was used at 3% WG. Following the coating, the tablets were stored in induction sealed (120 mL HDPE) bottles under 40°C/75% RH conditions for six months.

Table 1. Coating Parameters

Parameter	Opadry Clear	Opadry White
Batch Size (g)	1000	1000
Spray Rate (g/min)	10	10
Dispersion Solids (%/w/w)	10	15
Bed Temperature (C)	42	42
Inlet Air Temperature (C)	58	58
Air Flow (cfm)	123	123
Number of Spray Guns	1	1
Pan speed (rpm)	20	20
Atomization air (psi)	20	20

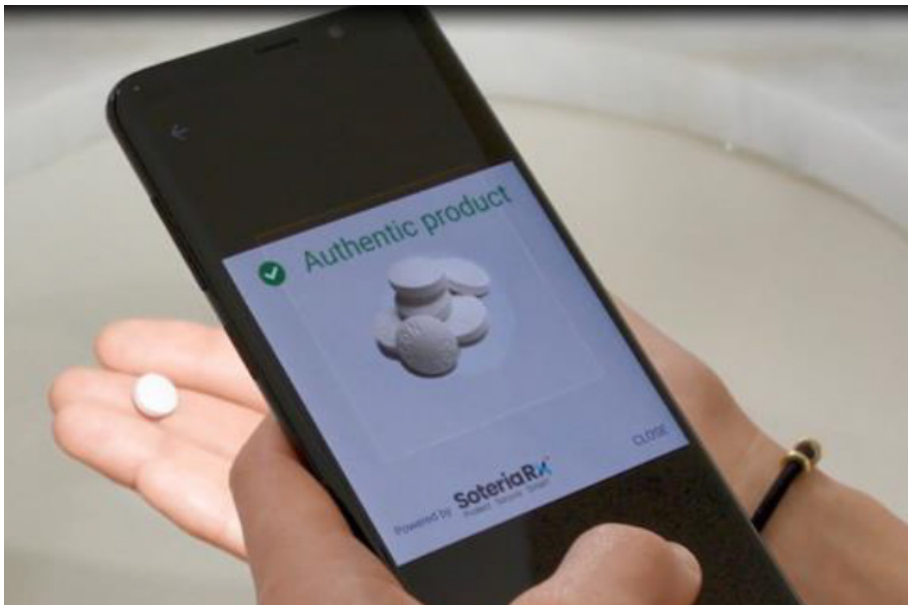
Authentication was performed through a custom-designed smartphone App. Tablets were considered fake or non-authentic if microtaggants were not detected on either face of a selected tablet. Fifty tablets from each storage condition were tested unless specified. The smartphone App took less than 10 seconds to authenticate a tablet.

Results

The physical appearance of tagged and untagged tablets for both clear and white formulations were comparable with no visible differences (Figure 1). The smartphone confirmed 100% authentication of tablets containing microtaggants in the coating, while the standard coated tablets showed no microtaggants present (Figure 2). Both clear and pigmented tablets with microtaggants showed 100% authentication during the accelerated stability studies.

Figure 1. Opadry Coated Placebo Tablets, With and Without Silica-Based Microtaggants

Figure 2. Authentication of Microtagged Opadry Coated Placebo Tablet Using Mobile Device



Conclusions

Tablets coated with an Opadry film coating containing microtaggants were authenticated using the smartphone APP and differentiated from tablets that did not have the microtaggant in the coating. The presence of the microtaggants could not be visually detected. Coated tablets showed excellent stability at accelerated conditions over six months. The study confirmed the viable application of silica-based microtaggants for on-dose authentication using smartphone verification. These smart medicines can authenticate and provide real-time data collection that will improve patient engagement, reduce medication errors, and identify fake or diverted medicines.

References

1. Kon SB, Mikov M. Counterfeit drugs as a global threat to health. Med Pregl. 2011;64 (5-6):285-90.
2. "Trade in counterfeit pharmaceutical products". PDF, Illicit Trade, OECD and the European Union Intellectual Property Office, 2020. https://www.oecd.org/gov/trade-in-counterfeit-pharmaceutical-products-a7c7e054-en.htm
3. Prusak B, To D, Performance and stability of an on-dosage authentication technology using molecular tags on the coated a model active. AAPS 360 (2021)

For more information, contact your Colorcon representative or call:

North America	Europe/Middle East/Africa	Latin America	India	China
+1-215-699-7733	**+44-(0)-1322-293000**	**+54-1-5556-7700**	**+91-832-6727373**	**86-21-61982300**

You can also visit our website at **www.colorcon.com**

Colorcon®