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MICRO-TAG: A NOVEL TECHNIQUE OF SECURITY IN PHARMACEUTICALS

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ABSTRACT

According to FDA estimates about 10% of all drugs sold worldwide are counterfeit. Annual global trade in counterfeit goods is estimated to be \$600 billion and growing. Counterfeit goods and drugs leads real threat to consumer safety as well as loss of companies brand value and profits. Till date, dosage authentication required forensic analysis in a laboratory which is a slow process involving application of sophisticated equipment. Now days to avoid counterfeiting of products many companies are coming with various techniques of product authentication. One of the newest, innovative securities ways is by applying micro-tags to the dosage. Unlike forensic systems, micro tags can provide quick, reliable, economical identification and authentication of a drug product in the field within a few minutes, without destroying the product. Not only this much, end-users also can monitor the tags with a simple, inexpensive, hand-held detection system. Each tag is unique and cannot be reverse-engineered by a counterfeiter. Micro-tag provides safe, easily implementable, reliable means of authentication of product.

INTRODUCTION: In today's global economy where high-demand products and pharmaceuticals are top targets among counterfeiters hence, brand security and product protection have become key components in ensuring public safety¹. The complexity of the pharmaceutical supply chain itself opens entry points for adulterated or counterfeit products. To strengthen security within the pharmaceutical industry, the US Food and Drug Administration (FDA) issued draft guidance last year with specific recommendations for manufacturers on the use of physical-chemical identifiers (PCIDs) in immediate release film coatings on solid oral dosage forms (SODFs)².

A PCIDs are the substance or combination of substances possessing a unique physical or chemical property that can identifies and authenticates a drug product or dosage forms.

Main aim of PCID's for Pharmaceutical manufacturers is to oppose entry of counterfeited drug product and also make easy to investigate if spurious drug product is entering in market³. Aside from compromising the safety of users and patients, manufacturers are adversely affected by loss of sale, brand value and loss of reputation when counterfeit product or device fail that have been branded with their company's trademark⁴.

These techniques of PCID's include^{2, 4, 5, 6, 7}:

- Visual Identification- unique colors, shapes, sizes, physical feature, unique tablet designs, logos and pearlescent film etc.
- Sensory Identification- flavors, taste and aromas with a unique profile.

- Covert Authentication- edible markers in the film coating which contain embedded images and customized characteristics.
- Packaging oriented- printed codes, serial numbers, 1D and 2D barcodes, hologram stickers, etc.

But many of these are proving inadequate protection as international crime organisations become more sophisticated and more accustomed to the traditionally used authentication technologies.² so needs combination of techniques for protect brand from counterfeited products. In order fight against counterfeited product companies started to make some own unique identity in products due to that it will not able to make duplicates of products and if unfortunately such things are occurring that must easily identify .Out of that Micro-tag is one of them which is most famous anticounterfeiting tool in PCID's in SODF's⁸.

What is Micro-tag? “The micro-tag is a marker, invisible to the naked eye, microscopic coverts (secret) information⁹. Micro-tag is incorporated onto the surface of a film-coated tablet or in a capsule, enabling visual authentication of the product” (Fig. 1).

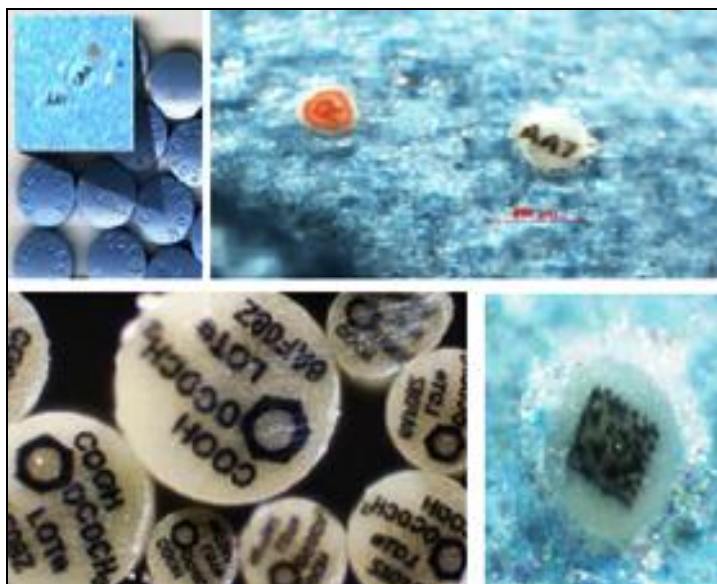


FIG. 1: PHOTOS OF SOME MICRO-TAGS

The micro-tags function as a unique hidden fingerprint embedded with information¹⁰. Micro-tag technology is used for the identification, validation, tracking, tracing, and authentication of pharmaceutical products¹¹.

The information included in each tag contains customized multiple layers of security, with unique indicia that is determined by the brand owner. Information might include manufacturer name, National Drug Code (NDC) number, manufacturer or product logo, a set of alpha-numeric codes such as lot and batch ID numbers, country codes, dates, patterns, shapes, symbols and 2D barcode for electronic scanability or other text as per need¹¹. That is specific to the product. These types of forensic-coded signatures offer an additional level of security that makes the technology virtually impossible to replicate by counterfeiters^{10,5}.

Micro-tags also can be incorporated as part of labels, bottles, paper and blister packaging. A future application for these covert identifiers is that they can then be linked to the packaging protection to verify authenticity of the packaging security. A link between the dosage and package will assist in ensuring the authenticity of the dosage that is ingested by the patient⁸.

Dimension of Micro-Tags: The micro-tags are customised to hold significant amounts of information in a space of 75–110µm, smaller than the diameter of a human hair (diameter about 100micrometers). Micro-tags can be created in random shapes and colors as per need.^{2,4} The information included in the micro-tags is customised to each client. The presence of forensic coded signatures is an added level of security that makes this technology virtually impossible to prepare same tag again.¹ Once micro-tag is get prepared it is Nearly impossible to replicate or reverse engineer.¹²

Material of construction of Micro-Tags: The FDA recommends that PCIDs should be constructed from permissible direct food additives generally recognized as safe (GRAS) or those listed in the FDA Inactive Ingredient Guide (IIG) under cGMP conditions and approved excipients materials within its limits^{13, 14, 6}.

How to introduce micro-tag in dosage form? This is accomplished by adding micro-tags to an immediate release film coating applied during the normal tablet film coating process of an approved film-coated product or incorporated into the shell of capsules, that are external micro-tag because it remains on surface¹¹.

Some time micro-tag are added at core, dosage form layers, that are called internal micro-tag is useful in forensic verification in liability and returns analysis^{2, 7, 15}. Micro-tags are can be applied to solid dosage forms as well as to primary and secondary packaging (bottles, blisters, printed labels), and package inserts to provide an "inside-out" approach¹¹.

That making it possible to build a multilayered anti-counterfeiting approach, and are "nearly impossible" to replicate or reverse engineer and In SODF's micro-tag can be added to the outside of tablets via sprayable inks or coatings or by using industry-standard pan coaters, without changing an existing process with added assurance that every dose is marked without any negative impact on productivity^{16, 2}. The approach enables pharmaceutical manufacturers to avoid any modification to the existing production processes as well as any costly capital investments for additional machinery¹.

Micro-tag authentication technologies fall into several distinct categories^{17,18}:

- 1) Optical tagging systems based on RF, VIS and UV additives to ink and packaging materials, including metameric tags containing hidden texts or images implemented in specific optical elements and/or holograms.
- 2) Magnetic tagging systems based on magnetic inks (magnetic barcodes, magnetic images)
- 3) Chip based RFID (Radio Frequency IDentification) or EMID - ElectroMagnetic IDentification) solution based on small laminated tags containing magnetic elements. (Flying Null's solution, various magnetic microwire solutions).
- 4) Chipless RFID solution based on quartz or metal microresonators (InKode solution). The technology is based on measurement of physical phenomena at the sub-molecular level such as Magnetic Resonance (Nuclear Magnetic Resonance - NMR, Nuclear Quadrupole Resonance - NQR, Electron Magnetic Resonance - EMR), which were not used yet in the market and are new effects on the anti-counterfeiting area.

- 5) Biomolecular systems based on the use of complex biomolecules (DNA). The correct choice of the concrete anti-counterfeiting solution is usually determined by the balance of those advantages and disadvantages which are immanent for each technological solution.

How to detection Micro-Tag in formulation? As micro-tags sizes from 75-100 μm and human eye cannot resolve image of less than 100 microns. Printed content is impossible to read as such^{16, 19}. The micro-tags become invisible to the naked eye once they are incorporated into a film coating; however, they are easily identified with specialized systems. These are simple, reasonably priced, hand-held optical tools that authenticate a product by magnifying the micro-tags at any stage following the coating process. The simplicity and portability of the system enables accurate, in-field detection within a matter of seconds without destroying the SODF sample. Tablets can be verified through blister packs using a portable spectrometer.

This system does not require sophisticated external databases, communication networks or integration into complicated data systems or laboratory sites to authenticate a product. All that is required is a visual confirmation that the micro-tags are present and contain the correct information by viewing them with one of the visualization tools^{1, 10}. It possible to detect and authenticate legitimate dosage forms and identify counterfeits using a simple microscope that works by magnifying the tag¹⁶. All that is required is a visual confirmation that the micro-tags are present and contain the correct information^{10, 14}.

Identified by parameters includes-shape, size, indicia, colors, chemistry, responsive, forensic interpreting coads⁷.

Why micro-tag technology preferred in PCID's? ¹

- Companies can utilise the information within the micro-tag for immediately understand a product's traceability.
- Owner can also use information to sheds light on the distribution practices once a product leaves the manufacturing site.

- At any point within the distribution network, the tablets can be traced and examined which can identify possible sources of counterfeiting.
- The micro-tags provides intelligence can be seen during a product recall. Instances have occurred where manufacturers have received more product back from a recall than was actually produced, leaving many unanswered questions as to the authenticity of the returned goods.
- From a track and trace perspective, the micro-tags can provide the technology to distinguish authentic product from adulterated supplies. The drug manufacturer can take a closer look at understanding where the product originated to gain insight as to how the product was handled in the field.

Advantages of Micro-tag technique:

- The micro-tags are applied directly to pharmaceutical tablets during the film-coating process for reliable placement on each and every tablet without changing any aspect of the existing film-coating process of an approved product. This flexibility can save ample costs in terms of additional machinery¹⁰.
- The micro-tags can be added to dosage forms without additional manufacturing steps so compatible with existing coating processes^{5,6}.
- Silica micro-tags can be produced inexpensively using the electrochemical etch of a silicon wafer so need vary less capital investments as compared to security proved by tag^{2,16}.
- Have no impact on dissolution, quality, stability on final product⁶.
- Micro-tags are toxicologically safe.
- Its simplest form authentication where a match provides a "self-authentication" of the solid dosage without the need for a sophisticated database for track and trace. A mismatch or tablet with no micro-tag indicia indicates a counterfeit replication of the drug¹¹.

- It is newly developing technique so modification can provide a great area for research.

Disadvantages of Micro-tag technique: It not easier for a patient or pharmacists to identify the product at a glance need visual aids needs specilised visualization instrument.

Main disadvantage of micro-tag solution is relatively short detection distances. At present the standard micro-tag reader detects the tagging substance in close proximity or at distances up to 10mm from the reader's probe head and may not be recognized in remote. All these features make the micro-tag solution less attractive for direct Track and Trace applications, but remain this solution the most sophisticated for anti-fraud protection¹⁸.

Micro-tag must possess following property^{3,13,16}:

- The micro-tag should not affect the identity, strength, quality, purity, potency, or bioavailability of the SODF.
- It contains practical recommendations for example, noting than PCIDs.
- Should not affect the release profile.
- They should be pharmacologically-inactive, relatively inert and toxicologically inactive.
- It must be there in limited quantity in formulation as per norms mad by FDA (Silica must be less than 2%)
- Loading must possible with both the clear and opaque coatings with no detectable change in tablet appearance.
- Spray nozzles of coating machine should performed well without clogging.
- coating performance must not alter.
- They must have high temperature resistance (with a melting point above 1600°C), meaning that chemicals, fuels, plastics, and metals can be tagged during their processing.

Because of many advantages and good applicability of micro-tag many companies now a days coming with these type of product security system such as of [®]mark [®] On-Dose ID[™], TruTag Technologies (TruTag[™])^{3, 13, 20, 21}.

Extremely well suited to the pharmaceutical and supplements industry, also is scalable to applications in a wide variety of markets, including semiconductors, consumer electronics, aircraft parts, medical devices, food and wine, textiles, and luxury goods.²⁰

CONCLUSION: As the occurrence of counterfeiting is continuing to grow, the industry needs technologies that can help it to reduce such issues and maintain trust with consumers. Micro-tag technology can provide means that do not require any complex electronic infrastructure requiring sophisticated data management for detection capability. Micro-tags is most simplified, safe and reliable technologies. The micro-tags are seamlessly integrated into existing tablet film coating manufacturing processes without any additional capital expense or system downtimes. These features, and the broad range of available compliant materials for constructing micro-tag technologies, provide brand owners with universal flexibility for protection, and the confidence that this micro-tag authentication technology is 100% reliable.

Incorporation of Physical-Chemical Identifiers into solid oral dosage form drug products for anticounterfeiting, opened the door to new security options for the pharmaceutical industry.

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