What is an Oral Thin Film (OTF)?

Oral Thin Films or Oral Disintegrating Films (or strips) can be medically defined as follows: “These are drug delivery systems that are quickly releasing the drug by dissolving or adhering in the mucosa with saliva within a few seconds due to it contains water-soluble polymers when it placed in the mouth cavity or on or under the tongue”. The sublingual mucosa has high membrane permeability due to its thin membrane structure and high vascularization. Due to this rapid blood supply, it offers very excellent bioavailability.

Many of us are familiar with the minty, breath-freshening strips that dissolve almost instantly on your tongue. Available at any convenience store, these thin strips don’t require chewing or swallowing. Imagine if these could serve as a means of drug delivery. With Oral Thin Films (OTFs), drug developers are achieving just that with surprising dosage accuracies and delivery times into the body.

OTFs are a drug delivery system that offer many advantages over more standard systems. These are essentially polymeric films that deliver therapeutic moieties into the oral cavity for absorption there or via the gastrointestinal (GI) tract. OTFs are easy to administer, they are quickly absorbed, when taken sublingually (under the tongue) the drugs directly enter the circulatory system, and efficiently deliver a larger proportion of the active compound per dose.

Oral Thin Films dissolve rapidly in the oral cavity and are absorbed much faster than orally ingested tablets or liquids. Especially for drugs which are metabolized extensively by the first-pass effect, an oral thin film formulation provides an opportunity for a faster-acting and better absorption profile.

As clinically proven time after time, depending on the specific drug and method used to create an OTF, the bioavailability absorption can be as little as 60% and as much as 94% with dissolution (the process in which a substance forms a solution) of the drug ranging from 80 – 97%.

Simply put, OTFs release a higher dosage into the bloodstream at a higher accelerated rate than virtually all forms of pills, edibles, tinctures, and most inhalable methods. Historically, edibles have an onset of 30-45 minutes and a bioavailability of 12-13%. Tinctures have an

onset of 12-15 minutes on average and a bioavailability of 15-25%. Inhalable products in any form have an onset of approximately 8-10 minutes and a bioavailability of 30% on average. **OTFs have an onset of 9-10 minutes and bioavailability of 80-90% on average.**

This means that an OFT can administer a lesser size dosage that results in having the same amount THC in the bloodstream that a person would have if they were consuming standard products currently on the market. The API (active pharmaceutical ingredient) will also stay far longer in the bloodstream at a higher concentrated rate.

Consider this example: When taking a 10mg THC gummy edible, the user is actually getting 1.2mg - 1.3mg of active THC in their bloodstream. And as any casual to medium usage cannabis consumer will agree, that is a pretty pleasant high with an onset time of 30-40 minutes. If we were to put 10mg of TCH in an OTF, the user would actually have 9mg entered into their bloodstream and feel it within 10 minutes straight to their head. That is 7.2x more THC. In this example, an OTF would only need to contain 1.5mg of TCH to deliver 1.35mg into the user's bloodstream. Further, dosage accuracies. An OTF's API dosage load is accurate to +/-1%. The dosage load of a gummy edible has an allowable inaccuracy rate of up to +/-10%.