

# The Adherent<sup>®</sup>

Technology Insights from Adhesives Research



Taking your products further.™

## Dissolvable Films: Flexible Formulation for Limitless Application Possibilities

ARx, LLC, a wholly-owned subsidiary of Adhesives Research, is a pioneer in the development and manufacturing of active dissolvable films for oral, topical and transdermal drug delivery. Since the company's first commercial launch of the dissolvable film platform for systemic drug delivery in 2004, the technology continues to evolve and gain the interest of researchers who are evaluating ways to apply the benefits of dissolvable films in new applications both in and beyond the realm of pharmaceuticals.

### Integrating Active Ingredients

Cast dissolvable films can integrate most available forms of active pharmaceutical ingredients (APIs), including micronized, granulated, salt and free-base forms. Both soluble and insoluble drugs have been successfully compounded into solutions, emulsions or suspensions which can be further processed into a dissolvable film.

Larger particle size compounds do present some constraints with regard to the final film thickness, but, in general, most API and nutritional compound particle size distributions fall within typical film production requirements. Active concentrations are possible up to 50% of the final unit mass; the proper dose is achieved by adjusting the size and thickness of the final film strip.

### Precise Format

Based on precision adhesive coating technologies used for decades in the transdermal industry, the manufacturing techniques for cast dissolvable films are well understood and lend themselves to holding exceptionally tight tolerances throughout the process in final individual doses and with unit tolerances as tight as  $\pm 2.5\%$  around



the potency target. Specialized coat weight monitoring systems and liquid deposition techniques enable film products to hold and maintain consistent cross and downstream uniformity during manufacturing. This continuous process monitoring also lends itself to process analytical technology initiatives and helps to identify any processing variability in real time.

### Flexible Formulation

The flexibility of the dissolvable film platform enables formulators to

evaluate a broad range of excipients and active ingredients for a wider range of available material sets to produce both an acceptable and stable product.

A number of the film's physical formats can be customized, including dissolution rates, thickness, material composition, taste-masking and API absorption rates, to broaden its potential for application.

### Topical & Wound Care Applications –

Films can deliver active agents, such as analgesics and other treatments, to targeted sites.

**Diagnostic Test Devices** – The controlled volume of reagents in a film delivers precise dosing for increased consistency and accurate test results.

**Binding Agents** – Dissolvable films are being considered in applications for enveloping active particles in multi-layer or combination systems to enable controlled release.

**Buccal, Sublingual & Mucosal Delivery Systems** – Layers of dissolvable films with tailored dissolution rates may be combined with bioadhesives for the controlled release of APIs.

**Gastro-Retentive Dosage Systems** – Water-soluble and poorly soluble molecules of different molecular weights can be contained in a film format to disintegrate within the GI tract.



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