

Lubrizon LifeSciences

# Transform™ Polymer Films: Rapid Drug Delivery Hydrogels

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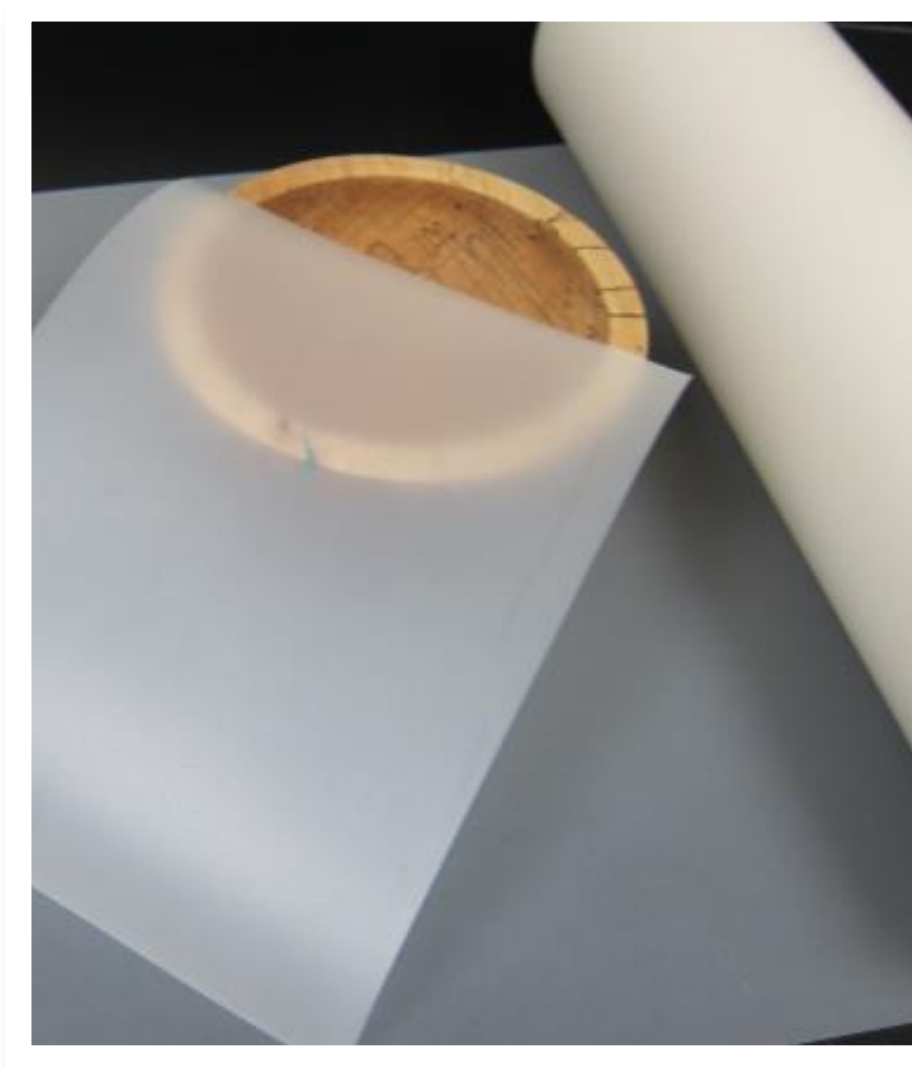
## Introduction

80% of people seeking medical attention are doing so because of pain. Globally, pain may affect as many as 1.5 to 2 B people which is more than diabetes, heart disease and cancer combined.

National Institute for Health and Care Excellence (NICE) gives clear guidance to healthcare professionals to prescribe topical products in the first instance for joint pain associated with osteoarthritis, in preference to oral NSAIDs, owing to concerns over systemic side effects caused by the long term use of oral NSAIDs.<sup>1</sup>

Despite the large amount of products on the market, consumers are still looking for relief.<sup>2</sup>

Transform™ Polymer Films are Transdermal Delivery Systems (TDS) that are compatible with a broad spectrum of Active Pharmaceutical Ingredients (APIs) and have excellent delivery of the API and are a new API reservoir for transdermal delivery of pain medication.



## Methods

Polymer films of 0.30 to 0.38 mm in thickness were used for the study. The films were loaded with lidocaine HCl and diclofenac sodium via hydration in excess aqueous based drug formulation. USP Apparatus 5 dissolution testing compared the novel thermoplastic polyurethane (TPU) hydrogel reservoirs to comparable commercial examples. Transdermal permeation test was performed on dermatomed human cadaver skin for 24 hours, and receptor fluid was taken at different time points and drug concentration was measured by HPLC.

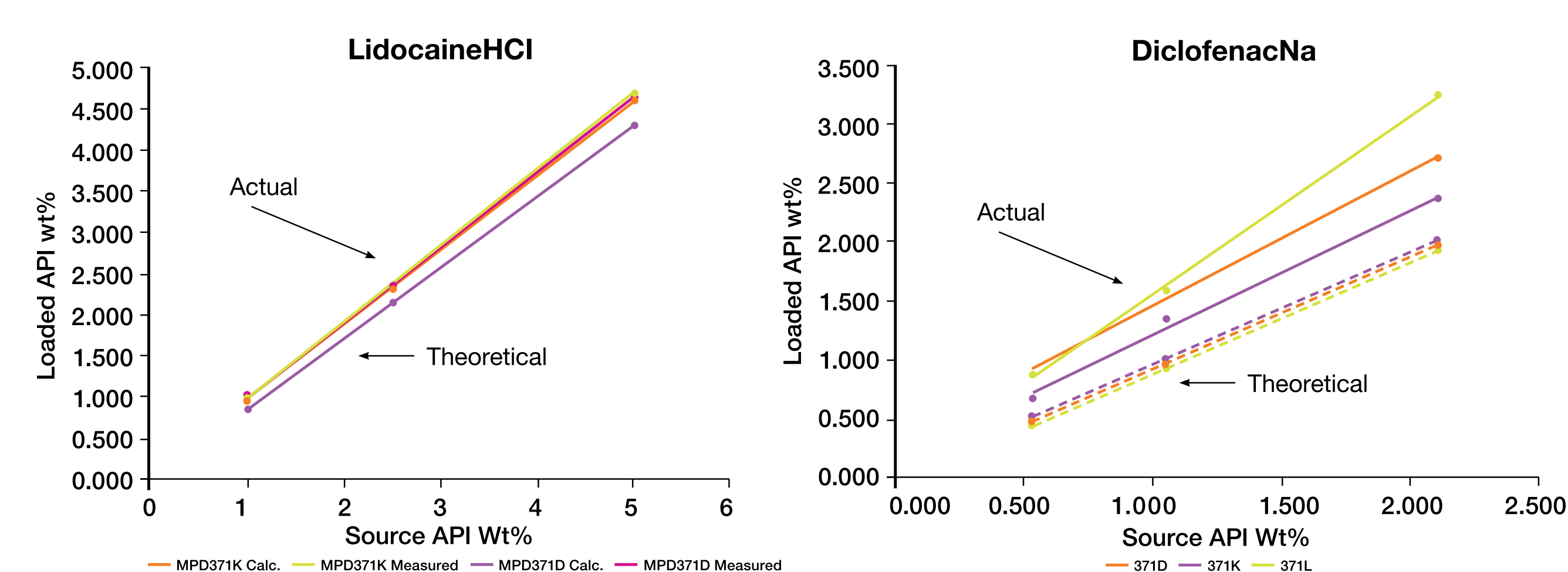


Figure 1. Loading of LidocaineHCl and DiclofenacNa in Transform™ Polymer Films.

## Results

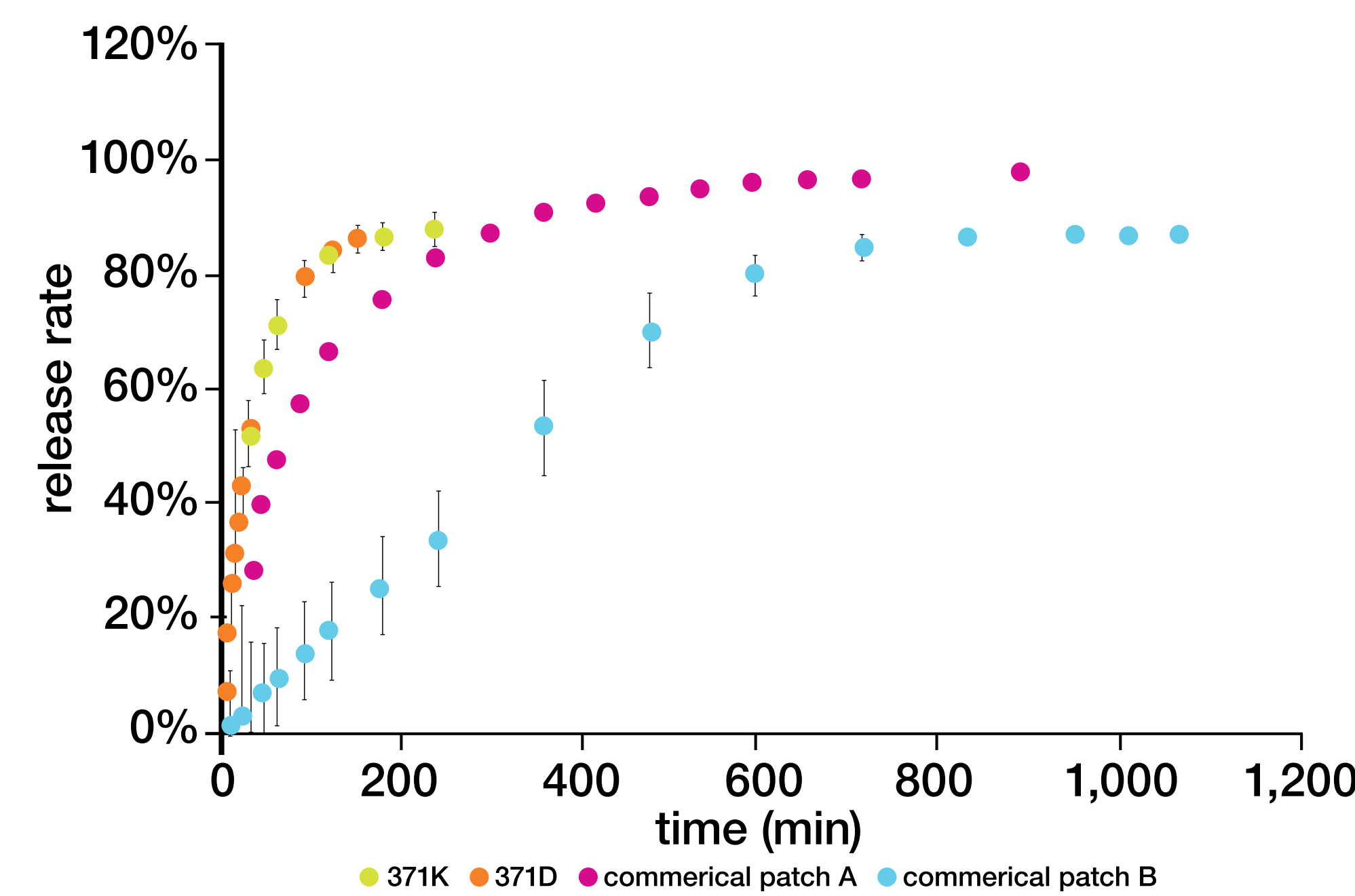


Figure 2. Diclofenac sodium release profiles from USP Apparatus 5 for Transform™ MPD 371K with Formulation 1 and 2, and Commercial patches A and B.

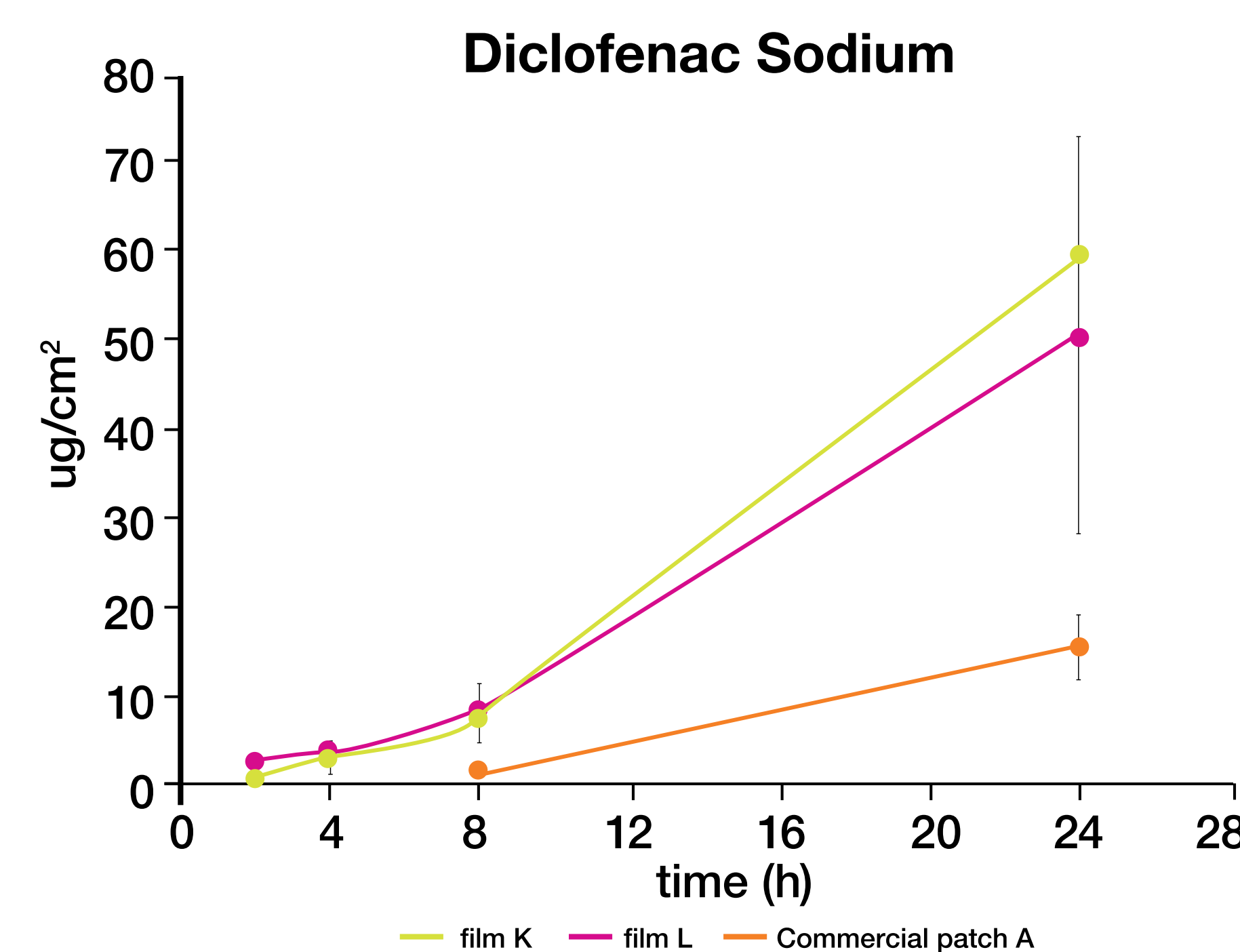


Figure 3. Diclofenac sodium transdermal permeation profiles from Transform™ MPD 371K and L, of Formulation 1 and Commercial patch A across human cadaver skin.

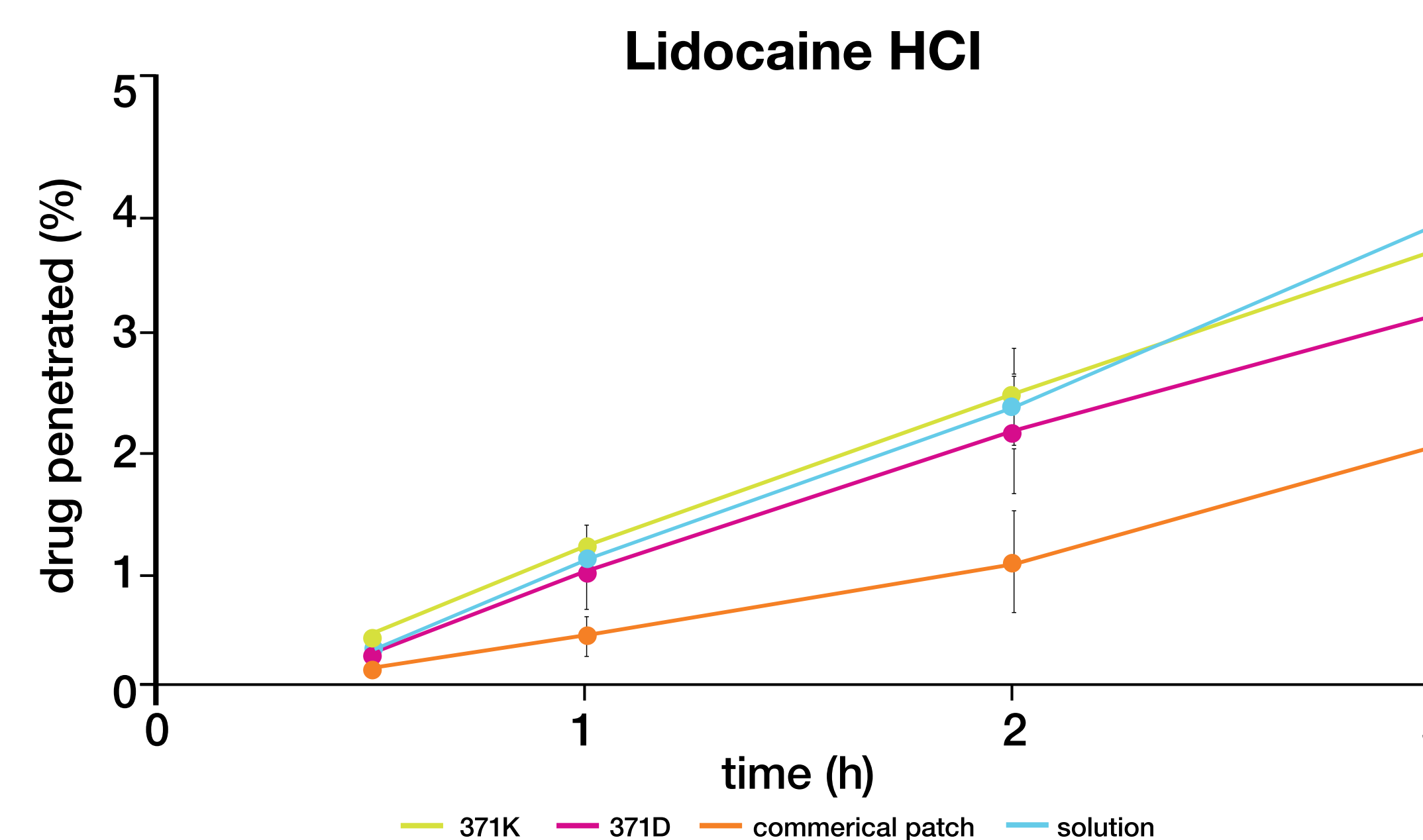


Figure 4. Lidocaine HCl transdermal permeation profiles from Transform™ MPD 371K and D, and commercial patch C across human cadaver skin.



Figure 5. Transform™ Films when hydrated has high transparency, conformability, and cool pleasant sensory on the skin during therapy.

## Discussion

Transform™ Polymer Films are a new component of Transdermal Delivery Systems (TDS) and serve as a reservoir and delivery matrix for TDS patches.

Transform™ is available as a dry film ready to load. There are several methods available for loading. These studies used immersion in simple aqueous formulations of API, humectant and preservative.

Transform™ polymer films (MPD 371K, D and L) absorb between 3 and 10 gm /gm fluid to give strong transparent hydrogel films (Fig. 5). Lidocaine HCl (5 wt%) and diclofenac sodium (1 wt%) (Fig. 1) are reliably loaded via hydration. The final drug loaded hydrogels release drug rapidly in Apparatus 5 sink condition (Fig. 2). Transdermal permeation testing via IVRT shows higher permeation through human cadaver skin of the APIs delivered by Transform™ films vs. commercial comparison (Fig. 3 & 4).

## Conclusions

- Transform™ Polymer films have been developed for rapid topical delivery hydrogels with high clarity, strong mechanical properties and good sensory.
- This film platform has been demonstrated with well-studied pain relief actives to show rapid and highly effective dermal delivery.
- This TDS platform provides innovative solutions for a new generation of topical delivery.

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