

IMPROVING THE DELIVERY OF COMMERCIAL PAIN MEDICATION

Research project breaks new ground in drug delivery speed and drug utilization

INTRODUCING ARx

ARx is a global market leader in oral and mucosal thin films and transdermal patches. We form productive partnerships with well-established as well as start-up pharmaceutical companies, focusing on both generic and branded drug applications. Successful commercial launches combined with flexibility in production capacity and bespoke research and development have reinforced our reputation as a trusted supplier of patient-centric drug delivery solutions.

THE CHALLENGE

The purpose of the research project was to test ways of enhancing the delivery of commercial pain medications. The goal was to improve drug onset (Tmax) and bioavailability compared to traditional sublingual tablet or buccal film formulations. The objective was to develop a novel product with clear advantages over existing dosage forms, ensuring it could be commercially scalable within an agreed timeframe.

THE METHOD

ARx's proven expertise in oral thin films provided a theoretical and practical springboard for launching the project. Two experimental prototypes of sublingual film, utilizing ARx's novel microdeposition technology, were created to test and compare against different dosage forms of commercial pain medication: a marketed sublingual tablet and a marketed buccal film. The samples were prepared using similar processes to ensure consistency and replicability.

Prototype BUP905054-1: sublingual film was designed to deliver an identical dose (2 mg) as a generic sublingual commercial pain medication tablet.

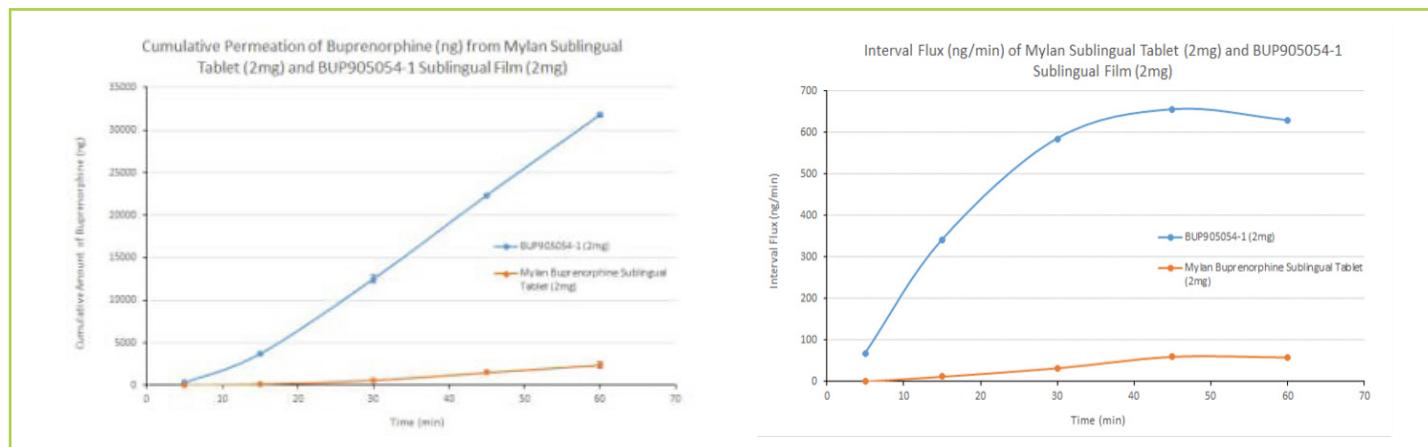
Prototype BUP905054-2: sublingual film was designed to deliver an identical dose (0.2 mg) as a branded commercial pain medication buccal film.

The following experimental parameters were kept consistent throughout the two studies:

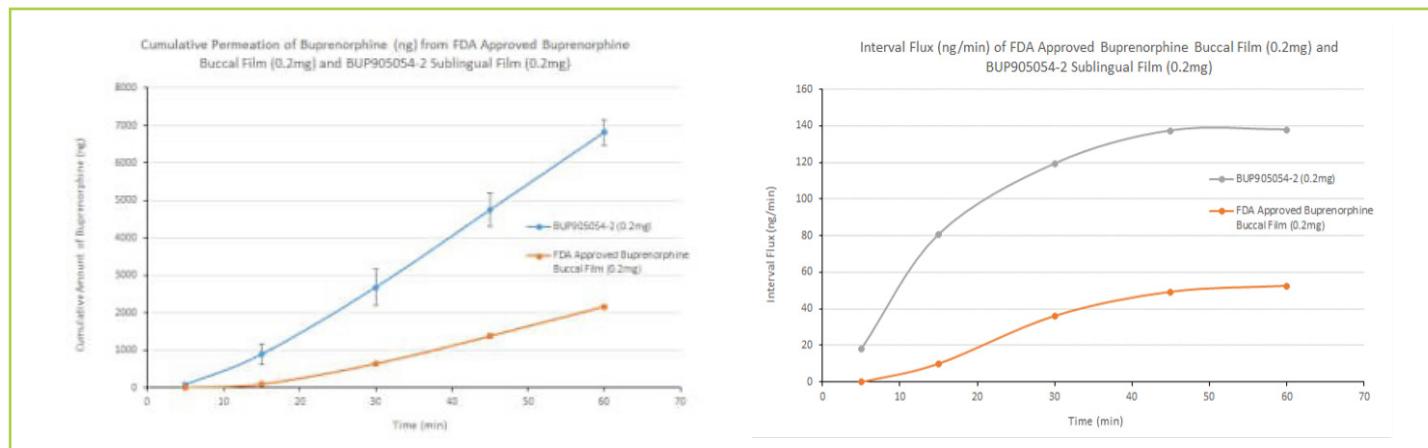
- A MatTek ORL-200 (EpiOralTM) 24-well plate containing oral tissue cultures was utilized as the diffusion membrane for the comparability study.
- The tissues were equilibrated in a 5% CO₂ chamber set to 37°C and 95% relative humidity.
- Dulbecco's phosphate buffered saline (DPBS) was used as the receiver media.
- Sampling time points were 5, 15, 30, 45, and 60 minutes.
- Full receiver media was replaced after each sampling time point.
- All samples were tested in triplicate. The reported values are an average of three replicates.
- The diffusion of commercial pain medication was quantitated using ultra high-performance liquid chromatography (UHPLC).

THE RESULTS

BUP905054-1 sublingual film delivered over 600 times more commercial pain medication in 15 minutes than the Mylan sublingual tablet:



BUP905054-2 sublingual film delivered over 8 times more commercial pain medication in 30 minutes than the branded commercial pain medication buccal film:



THE BENEFITS

The results clearly demonstrate that ARx's micro-deposition technology allows more drug to permeate through cell culture tissue, potentially enhancing the therapeutic effect. Microdeposition not only requires less drug but also facilitates faster entry into the systemic circulation. Benefits include cost savings, reduced potential for abuse and adverse events, and quicker pain relief for the patient.

CONTACT

For further information on ARx's novel sublingual delivery technologies or to learn how your active can be delivered in a more efficient manner, **please contact:**

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