



CASE STUDY

Enabling Long Term Pain Relief With Innovative New Technology

There was a need for an extended release acetaminophen tablet that could be easily broken without exposing patients to inconsistent, even harmful levels of drugs. FLEXITAB™ technology held the answer.

To find out more about how TEDOR can help make your next project a success, contact Terry Novak, Chief Operating Officer, at (862) 207-1262

The Challenge

Acetaminophen, one of the most commonly used pain relievers on the market, is used to treat mild to moderate pain—including headaches, muscle aches, arthritis, backache, toothaches—as well as to reduce fever.

Consistent dosing is key when taking acetaminophen, as the drug is not without its drawbacks and risks: taking more than recommended does not provide any additional relief and can lead to liver damage.

Therefore, there was a clear need for extended release acetaminophen providing simple titration and twice-daily dosing. However, conventional extended release tablets 'dose-dump' when broken, exposing patients to harmful levels of drug. A tablet that could be easily broken without exposing patients to inconsistent, even harmful levels of drugs, would need to be developed.

The Solution

ACETAFLEX ER™, a breakable extended release form of acetaminophen, was developed using FLEXITAB™ technology. FLEXITAB tablets can be broken into pieces with no change in performance, therefore providing all the convenience of extended release without the risk.

FLEXITAB tablets, like ACETAFLEX ER, are robust yet can be precisely broken with just one hand, leading to easier to swallow doses. High dosage strength products may be difficult to swallow for the young and the elderly, but breakable tablets address this issue directly.

The Outcome

By simplifying titration for the patient and the physician, ACETAFLEX ER provides multiple strengths from the same tablet. This results in fewer medication errors and fewer tablets to deal with.

A 400-patient Phase II study have demonstrated that ACETAFLEX ER provides pain relief in less than 30 minutes, analgesia maintained for up to 12hr versus placebo, a patient efficacy rating of "good to excellent" of 70%, and excellent tolerability.

ACETAFLEX ER and other products using FLEXITAB technology are available now for licensing.

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