Accu-Break Pharmaceuticals, Inc. SETTING THE STANDARD FOR DOSE FLEXIBILITY









Patented Pharmaceutical Tablet Technologies for Accurate and Customized Dosing



Accu-Break®

Innovative Pharmaceutical Tablet Technologies

Accu-Break Pharmaceuticals, Inc. has developed a suite of proprietary pharmaceutical tablet technologies that can be applied to almost all formulations to create dose-adjustable tablets. These patented and patent pending technologies can sharply differentiate a product with clinically relevant enhancements by giving physicians and patients unprecedented dose flexibility within a single tablet.

Dose Flexibility: A Growing Need

The growth of the elderly population, the high cost of prescription medications and the trend towards individualized dosing have created a market opportunity for dosage forms that can be easily adjusted to meet precise dosing needs. Easily and accurately divisible tablets are practical for many therapeutic classes and medications, including antihypertensives, antidiabetics, narrow therapeutic index medications (e.g. warfarin), opioid analgesics, antidepressants and antipsychotics.

The Accu-Break Advantage

The key to the suite of Accu-Break technologies is the use of a unique drug-free layer within each tablet that serves as a breaking region. When subdividing Accu-Break tablets, the break occurs in the drug-free layer. This guarantees a precise smaller dose every time, eliminating issues with crumbling and unpredictable doses.



Broad Applicability

Accu-Break technologies are suitable for most single and combination agent formulations, and for standard and controlled release formulations. The technologies are also useful for combining incompatible formulations into a single dosage form.

Patented Technologies

U.S. issued technology patents and pending patents extend until at least 2025, with numerous additional patents pending worldwide.

Life Cycle Management Solutions

Life cycle management (LCM) is an important strategy for extending and maximizing the value of a product. In addition to adding a functional improvement to oral dosage forms, applying the Accu-Break technologies will serve to differentiate a product in a competitive pharmaceutical marketplace. Among the many LCM solutions to consider are:

- Tablets that are easily divisible into precise smaller doses, including halves, thirds, quarters or more
- Innovative combination drug tablets for maximum dose flexibility
- Divisible controlled-release tablets



Benefits to the Manufacturer

- Patent-protected and patent pending technologies
- Low cost, low risk implementation
- Clinically relevant product enhancement
- Competitive market advantage
- Benefits easily conveyed to end users
- Anti-counterfeiting properties

Individualized Dosing Just Got Easier



Now there's Accu-Break

Accu-Break technologies allow for easy and accurate dose adjustment











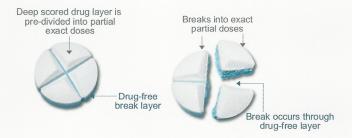


Accu-Break Technologies for Single Agent Drugs

Many widely prescribed medications undergo titration and/or dose adjustments. However, the majority of oral dosage forms are only available as either unscored tablets or capsules, making dose adjustments difficult, costly and potentially unsafe. This leaves patients generally with two options for adhering to the prescribed dose: (1) paying for a new prescription for the required dose (if it exists) or (2) splitting their tablets to achieve the required dose, assuming the medication is sold as a tablet and not as a capsule. The first option is costly and time-consuming while the second option can be difficult and risky, especially if the tablets are unscored.

With Accu-Break technologies, patients and physicians can easily and safely adjust doses with accuracy.

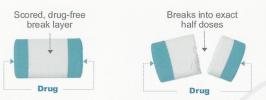
Accu-B™ Bi-Layer Technologies



Multiple scoring options



Accu-T[™] Tri-Layer Technologies



Advantages

- Ease of subdivision, accuracy of smaller doses
- ✓ Preferred over standard dosage forms by physicians
- Low risk, low cost implementation
- ✓ Range of doses with a single tablet



Accu-Break Technologies for Combination Drugs

Combination drug products have become increasingly popular and accepted as a means to simplify therapy and improve patient adherence. The drawback, however, is the lack of dose flexibility with traditional fixed-dose combinations. Accu-Break technologies offer novel patented solutions for combining the convenience of a fixed-dose combination with the dosing freedom of separate prescriptions.

This technology can also be useful for combining incompatible actives within a single tablet.

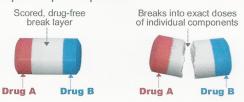
Accu-B Fixed Dose Combination Tablet

The patent pending Accu-B technologies allow for the creation of fixed-dose combination tablets that are easily divided to titrate the combination.



Accu-T Split-Dose Combination Tablet

This truly novel and patented combination tablet design offers the convenience of a fixed-dose combination with the flexibility of separate prescriptions.



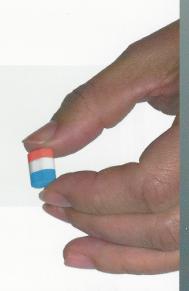
Accu-T Fixed Dose Combination Tablet

Accu-T technologies allow for the creation of fixed-dose combination tablets that are easily divided to titrate the combination.





- Patents provide life cycle management options
- Practical improvement over existing fixed-dose combinations
- Competitive advantage in the marketplace
- Low cost, low risk implementation





Accu-Break Technologies for Controlled-Release (CR)

Controlled release formulation products are popular for reducing the pill burden on patients. However, dose adjustment through tablet splitting is discouraged for most CR products due to the risk of changing the release kinetics of the tablet.

Accu-Break technologies solve this problem by creating divisible CR dosage forms. These CR tablets when subdivided result in precise half doses with the same release kinetic as that of the whole tablet.

Accu-T for CR Products

 Easily subdivide CR tablets in half without changing the release kinetics



 Innovative layer tablet for CR and immediate-release (IR) products

mechanisms



- ✓ Split CR tablets without changing release kinetics
- Low-cost, low risk technologies
- Innovative differentiation for CR products
- Titrate CR medications
- ✓ Ability to separate IR and CR components from each other

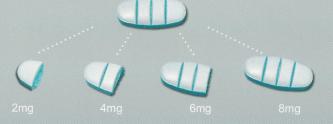
Accu-Break Technologies for Clinical Trials

Creating Efficiencies in the Drug Development Process

The development of a new drug can take anywhere from 10 to 15 years from discovery to FDA approval, with a cost of \$500 million to \$1 billion. Phase 2 dose-ranging trials represent a major portion, in both time and money of the clinical trial process.

With Accu-Break technologies a single tablet can cover multiple doses which can reduce clinical trial supply needs and be valuable during dose-ranging trials. This may save time and money during the development process.

Example: 8 mg Accu-Break tablet



Accu-Break Technologies for Veterinary Medicines

Pet ownership worldwide continues to rise, with over 60% of U.S. households having at least one pet. Due to advances in veterinary technology and spending on preventative healthcare, pets, like their human counterparts, are living longer. As pets age, they develop a wide range of medical conditions similar to humans, among them heart disease and diabetes.

Dose accuracy and flexibility in the veterinary sector has been a long-standing unmet need. Animal doses vary substantially from human doses and, quite commonly, the former are not available in the required dose strengths.

Accu-Break provides solutions in veterinary medicine by accommodating weight variations and among pets. Accu-Break technologies allow for appropriate dosing from the smallest cat to the largest dog.



