

## I N T R O D U C T I O N

Banner is a global polymer-based drug delivery and specialty pharmaceutical company. We are committed to researching, developing and producing unique oral dosage forms for the Pharmaceutical Health Care Industry. Through our innovative technologies and products, and with the dedication of our employees, we seek to improve the quality of life for our global community.

As a world leader in developing innovative drug delivery systems and patented technologies, Banner offers breakthrough technologies such as Soflet® Gelcaps, Chewels™ chewable gels, LiquiSoft™, chewable liquid filled softgels, Enteri-Care® enteric softgels, Versatrol™ controlled release softgels, and EcoCaps™ non-animal softgels.



 **VERSATROL™**  
controlled release softgels

Shingai Majuru, Ph.D.  
Tatyana Dyakonov, Ph.D.

Controlled drug delivery technology development represents one of the frontier areas of science, involving multidisciplinary scientific approaches that all contribute to human health care. In drug administration, controlled release dosage forms offer numerous advantages compared to conventional immediate release dosage forms, including potential for greater effectiveness in the treatment of chronic conditions through more predictable kinetics, reduced side effects and toxicity by minimizing peak plasma concentrations, greater convenience and higher levels of patient compliance due to simplified dosage schedule.

Controlled release products offer a simplified dosing regimen by providing a prolonged release of a drug while maintaining its blood concentration within therapeutic limits for a longer period of time compared to immediate release dosage forms. Additional advantages of controlled release dosage forms include circumventing problems in drug absorption or metabolism, optimizing therapy itself and providing a life cycle management opportunity. As a result of the benefits stated above the controlled drug delivery market continues to experience growth.

In 2007, the global controlled drug delivery market was estimated to be worth over US \$17 billion and, of this amount, oral controlled release dosage forms were estimated to account for 90% of sales and demonstrated more than 2% year-on-year growth<sup>1</sup>. The growth of con-

trolled release technology continues to be fueled by life cycle management opportunities helping to offset the impact of generic erosion. In the course of product development pharmaceutical companies do not typically make the additional investment to develop a controlled release version of a product while the immediate release version is still under patent protection<sup>1</sup>. As a result of this, sizable market opportunities exist in the development and application of controlled delivery technologies for both approved and new pharmaceuticals still under development.

The dosage forms typically used for oral controlled release are tablets and two piece hard gelatin capsules, however soft gelatin capsules are gaining increasing use. A soft gelatin capsule (softgel) dosage form offers the possibility of using a liquid, suspension or emulsion in a solid oral dosage form. The flexibility for formulating poorly soluble drugs as solutions, suspensions or emulsions leads to greater latitude in improving drug absorption compared to delivery from a tablet or powder form. Softgels are therefore the ideal dosage form for delivery of compounds with poor solubility and oral bio-availability. Accordingly, Banner's development of Versatrol™ technology offers the benefits of a softgel with the advantages of controlled release technology (CRT) to overcome formulation problems and maximize efficacy and speed to commercial development.

## ADVANTAGE OF CONTROLLED RELEASE TECHNOLOGY IN SOFTGEL FORM

Among the advantages of the soft gelatin dosage form is that it is preferred by patients compared to tablets and two piece hard gelatin capsules. According to one survey<sup>2</sup>, approximately 90% of respondents strongly preferred clear softgels over other dosage forms in virtually all the areas investigated. Notably, the overall preference of softgels was mainly because they were perceived as easier to swallow compared to other oral dosage forms. The advantage of softgels for pharmaceutical companies mainly comes from reformulation into this unique dosage form and

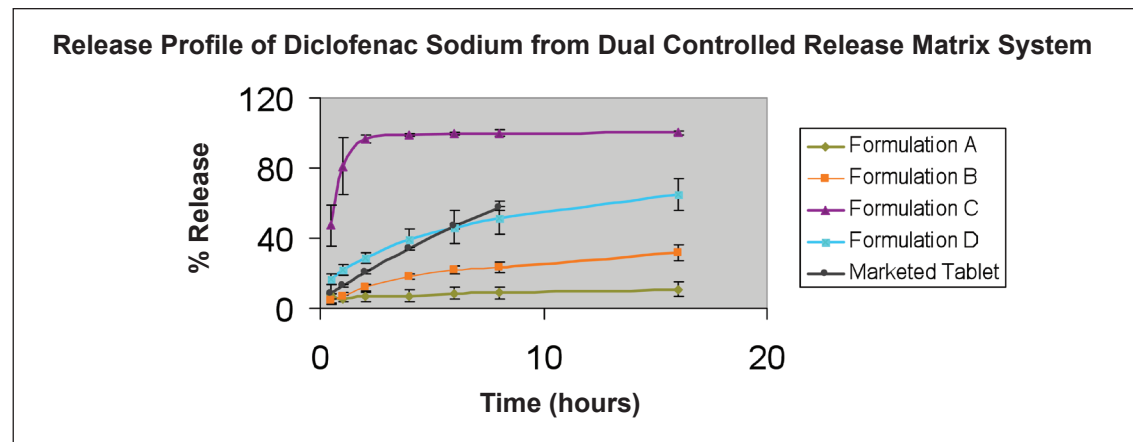
thus allowing for the drug to be promoted with a new brand name, for a new indication, at a dose level that is not easily copied by generic versions of the original drug and in a new form that is preferred by consumers. To this end, Banner has developed new softgel technologies that not only offer specific benefits over the standard softgels, but also provide additional patent protection to the compounds they deliver. One of these technologies is the Versatrol™ controlled release technology.

<sup>2</sup>Jones III J.W., Francis J.J., Softgels: Consumer Perceptions and Market Impact relative to other Oral dosage forms, *Advances in Therapy*, 17(5), 2000

## VERSATROL™ YOUR COMPLETE SOLUTION

Banner's Versatrol™ technology is a uniquely innovative technology that can provide controlled release for a wide range of drugs by incorporating the drug in a lipophilic or hydrophilic matrix that is then incorporated into a soft gelatin shell. The technology is versatile because, depending on the physico-chemical properties of the drug, either a suspension or

emulsion formulation can be developed. For lipophilic drugs, a suspension formulation is utilized while for hydrophilic drugs an emulsion formulation is preferred. Importantly, by applying varying combinations of hydrophilic and lipophilic matrices any desired release profile can be achieved including a dual-release profile as shown in the Figure below.



The utility of the Versatrol™ technology is greatly enhanced because it combines a versatile controlled release technology with the benefits of a customer preferred dosage form.

## K E Y F E A T U R E S

Banner Pharmacaps Inc.

4125 Premier Drive

High Point, NC 27265

t 336.812.8700

f 336.812.8777

Banpharm.com



 **VERSATROL**<sup>™</sup>  
controlled release softgels

- Novel, innovative controlled release technology system, unique to the market
- Depending on the physico-chemical properties of the compound, an emulsion or suspension is chosen as the formulation
- Varying proportions of hydrophilic and hydrophobic components can be added to the formulation matrix to provide a tailored release profile including a dual release profile
- Unique matrix formulations which can accommodate lipophilic and hydrophilic drugs
- Good option for moisture sensitive drugs, due to inherent hydrophobic environment in the fill
- Consumer-preferred dosage form

## C O N C L U S I O N

Versatrol™ is a unique oral controlled release technology for the pharmaceutical market place. When combined with softgels, controlled release technology provides a consumer-preferred dosage form with the ability to tailor release profiles for a wide variety of drugs. Versatrol™ offers controlled release formulations with the benefits of greater effectiveness in the treatment of chronic conditions by reducing side effects

through minimizing peak plasma concentrations, and greater convenience leading to higher levels of patient compliance due to a simplified dosage schedule. Versatrol™ technology can be applied early on in pharmaceutical product development, leading to the parallel development of immediate release and controlled release formulations to maximize market exposure.