



## **API Formulation & Testing: Is There a Better Way?**

Today's drug development has reached an impasse, as no single drug delivery form can be the standard for all types of medication. While research and development drives new formulations, the technology used to administer those formulations and bring them to market is lagging. For many highly potent and highly toxic substances, capsules offer ideal containment, superior dissolution and higher absorption rates when compared to other orally ingested dosage forms. Moreover, capsules offer the quickest time to market out of any oral delivery form, reducing the time to market by up to 18 months and offering a superior alternative to API formulation and testing.

### **Clinical Trials Create Wasted Motion**

New API's are traditionally formulated in multiple different delivery forms prior to going to market. Many drugs are tested in dosage forms that will never see the market shelf, causing significant delay in the drug development process.

Liquid filled capsules are a superior dosage for the new types of highly potent and highly toxic drugs being synthesized today because of the better bioavailability rates they offer. Utilizing capsules during development can eliminate a significant amount of time, as other inferior and less bioavailable dosage forms can be eliminated from the testing timeline.

### **Meet FM-CAPS® - Reducing Up To 18 Months**

The future of API formulation and testing lies in FM-CAPS®. Developed by leading hard capsule manufacturer, CapsCanada®, FM-CAPS® offer a complete, "all dye" solution essentially enabling pharmaceutical brands to reverse engineer brand formulation by removing ingredients from their formulation rather than adding them.

FM-CAPS® were designed specifically to reduce time to market and deliver a distinct competitive advantage. By containing all possible dyes and additives, FM-CAPS® eliminate extraneous regulatory interaction and preserve existing

stability studies conducted during early-stage clinical development. Shorter time to market naturally translates to noticeable labor and cost savings.

Traditional capsule development and testing is conducted in standard clear capsules. If any change is made to the API formulation, including additives used in the coloration of the final market ready product, the entire development process starts over and the new formulation must be resubmitted to the regulatory agency with the additional color dyes.

**About the company:**

CapsCanada® is a world leading manufacturer of pharmaceutical grade two-piece capsules. Clients include the most prestigious companies around the world.

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