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ACETAFLEX™: A novel breakable 12 hour extended release acetaminophen formulation

Acetaminophen (Paracetamol or APAP) is a low potency analgesic used to treat a range of pain indications. Thus, APAP may be infused intravenously for postoperative pain and combined with codeine or tramadol to treat mild to moderate pain. Best known of APAP's uses however is the treatment of mild pain where it is available over the counter as immediate release (IR) or extended release (ER) tablets providing up to 8 hours of relief. Despite the long history of this medication APAP, unlike other products in this market, has never been available as a 12 hours duration ER tablet. Here we report the development of a novel breakable extended release formulation of APAP developed using FLEXITAB™ technology to address this unmet need. FLEXITAB 12 hours controlled release tablets (ACETAFLEX™) are 750 mg bilayer matrix tablets designed to provide both early onset and sustained analgesia. In a placebo controlled 403 patient Ph II human proof-of-concept study to assess the safety and efficacy of the tablets in a postoperative dental pain model, pain intensity difference (PID) and pain relief (PAR) scores were statistically greater for ACETAFLEX™ compared to placebo beginning at 15 minutes and continuing through 12 hours supporting that the analgesic effect of the tablets was maintained for this period. In addition the study medication was well tolerated with no serious adverse events being reported; one placebo-treated subject withdrew from the study due to an adverse event (emesis). Breaking of the tablets resulted in little to no change in their drug release rate which was also maintained in the presence of ethanol (40% wt/wt) whether intact or divided along the score.

Biography

Damon Smith is the Founder and CEO of Altus Formulation, a Montreal based Drug Development Company. He holds a PhD in Biological Chemistry and has over 27 years of experience in start-up to commercialization companies in the UK, Australia and North America.

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