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Optimization of a new controlled release oral dexamethasone formulation

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Ketoprofen, (RS)2-(3-benzoylphenyl)-propionic acid, is a member of propionic acid class of nonsteroidal anti-inflammatory drugs (NSAIDs) and has analgesic and antipyretic effects. It is known that, the optically pure S(+)-enantiomer (dexketoprofen) with its trometamol salt is rapidly reabsorbed from the gastrointestinal system, with rapid effects. Racemic ketoprofen is used as an analgesic and an anti-inflammatory agent, and is among the most potent in vitro inhibitors of prostaglandin synthesis, but also have an association with higher risk of serious gastrointestinal bleeding incidents than other NSAIDs. The analgesic effect is due to the S (+)-enantiomer (dexketoprofen), while the R(-)-enantiomer does not have analgesic activity. Because the R(-)-enantiomer seems to have ulcerogenic activity, at least in rats, the the hypotesis is that use of dexketoprofen alone should produce equivalent analgesia to double-dose ketoprofen (or the same effect as ketoprofen, at half the dose), but at lower risk of toxicity. Clays have been one of the more important industrial minerals; and with the recent advent of nanotechnology, they have found multifarious applications and in each application, nanoclays help to improve the quality of product, economize on the cost and saves environment. It contains various materials with layered structures. One of those natural materials is bentonite. The layered structure featured by bentonite is called montmorillonite (MMT). MMT is a naturally occurring 2:1 phyllosilicate, capable of forming stable suspensions in water. It has been shown that individual use of Montmorillonite exhibits digestive system effects such as anti-acid, protecting digestive system and ceasing diarrhea. At the same time, it is known to exhibit detoxing effect by absorbing toxic materials inside the digestive tract, due to the layered structure it possess. In the field of dermatology, it is used as a stabilizer in cosmetic creams, powders and emulsions. MMT has a layered structure and its interlayer is suitable for uploading medicines. It is well known that controlled release medicines are prepared using MMT. In our study, commercially available dexketoprofen trometamol was separated from its trometamol salt form by hydrolysis and converted it to its base, dexketoprofen. Dexketoprofen was uploaded to MMT which is reduced to nano-size. As a result of our study, it was determined that 8 g of MMT is capable of uploading 50 mg of dexketoprofen, and the particle size was below 200 nm.

Recent Publications:

1. Gaskell H et al. (2017) Single dose oral ketoprofen or dexketoprofen for acute postoperative pain in adults. The Cochrane Library, 2017.
2. Strawhecker, K. and E. Manias, Structure and properties of poly (vinyl alcohol)/Na⁺ montmorillonite nanocomposites. Chemistry of materials, 2000. 12(10): p. 2943-2949.
3. Cui, F., et al., Biodegradable nanoparticles loaded with insulin-phospholipid complex for oral delivery: preparation, in vitro characterization and in vivo evaluation. Journal of controlled release, 2006. 114(2): p. 242-250.
4. Carretero, M.I. and M. Pozo, Clay and non-clay minerals in the pharmaceutical industry: Part I. Excipients and medical applications. Applied Clay Science, 2009. 46(1): p. 73-80.
5. Senthil, V., et al., DEVELOPMENT AND CHALLENGES FACING FOR INSULIN ORAL DELIVERY. International Journal of Pharmaceutical Sciences and Research, 2013. 4(7): p. 2576.
6. Dong, Y. and S.-S. Feng, Poly (d, l-lactide-co-glycolide)/montmorillonite nanoparticles for oral delivery of anticancer drugs. Biomaterials, 2005. 26(30): p. 6068-6076.

Biography

Bilgesu Beria Sevim was born on 8 December 1994 at Istanbul, Turkey. She live in Istanbul. She has done her internship programs at different pharmaceutical areas such as pharmacy, hospital and pharmaceutical industry. Now, she is completing the Bachelors degree Program in Pharmacy at Bezmiâlem Vakıf University. Her research interests include nanotechnology and biotechnology.