Abstract:

Lornoxicam is a NSAID of the oxicam class and it has the same side effects of this group when taken orally. In attempts to avoid the systemic side effects of lornoxicam (e.g. gastric irritation) and to achieve sustained release of the drug, several buccal patch formulations containing lornoxicam were prepared using different polymers and were evaluated for in-vitro characteristics in part I of this study. In the current study, the selected formulations (based on the previous in-vitro data) are evaluated for in-vivo performance using experimental animals and clinical efficacy on human volunteers. Pharmacokinetic parameters were assessed following application of the selected patches in rabbits. A comparative clinical study was conducted on patients with post-operative pain and edema following maxillofacial operations. The results of the in-vivo animal experiment showed that lornoxicam formulated in different buccal patches was successfully delivered to the systemic circulation and showed high absolute bioavailability of lornoxicam. The clinical study results revealed that sodium carboxymethyl cellulose (NaCMC, 3%) formulation applied to the buccal mucosa was slightly better or equally effective to the orally administered commercial oxicam product (Feldene Flash® tablets) in reducing pain level, swelling and tenderness within a period of 4 days with no observed side effects. These findings suggest that lornoxicam administered in this buccal patch may present a potential therapeutic use as a strong anti-inflammatory and analgesic agent.

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