

Design, Development and *In Vitro-In Vivo* Study of Colon Specific Fast Disintegrating Tablet Based on Time Dependent Approach

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SUMMARY. Targeted delivery systems for treatment of Inflammatory bowel disease (IBD) are designed to increase local tissue concentrations of anti-inflammatory drugs from lower doses compared with systemic administration. The objective of this study was to formulate and evaluate an oral system designed to achieve site specific and instant drug release in colon for effective treatment of IBD based on time dependent approach. The system consists of core tablet containing model drug diclofenac sodium, superdisintegrant sodium starch glycolate, and coated with pH independent polymer Eudragit RSPO to achieve different total percentage weight gain. Drug release studies were carried out using changing pH method. Placebo formulation containing barium sulphate in the tablet was administered to human volunteers for *in vivo* X-ray studies. *In vitro* studies revealed that tablet with 5 % coating level release the drug after 5 h lag time corresponding to the colonic region. Tablets with 5 % coating level could maintain their integrity in human volunteers for 5 h, approximating colon arrival time and release the drug instantaneously. Colon targeting and instant drug release for 5 % coating level was due to swellable hydrophilic polymer, which is responsible for a lag phase preceding the onset of release and the immediate release effect of superdisintegrant. It was observed that as coating level increases, lag time also increases. This is because of increased diffusion path length and tortuosity at higher coating levels. *In vivo - in vitro* study reveals thickness of coating of Eudragit RSPO play an important role in colon delivery and tablet with superdisintegrant and 5 % coating level achieved the desired performance of the colon targeting.

KEY WORDS: Colon targeting, Diclofenac sodium, Eudragit RSPO, Inflammatory bowel disease, Superdisintegrant.

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