

Research Title	Development of 5-aminosalicylic acid film-coated tablets for colon-specific drug delivery
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Abstract

Combinations of Eudragit RS and polygalacturonic acid (PGA) or its potassium and sodium salts, when applied as a film coat has a potential value as a colon-specific delivery system. Dispersions of PGA in Eudragit RS were used as the film former for coating of 5-aminosalicylic acid (5-ASA) tablet cores. Drug release behaviors were assessed, *in-vitro*, under simulating conditions in term of pH and time to *in-vivo* during their transit to the colon. Negligible drug release occurred during first 5 hours where the coated tablets were in stomach and small intestine. After that, the pectinolytic enzymes were added into the pH 6.8 medium in order to simulate the *in vivo* condition where there is the digestion of bacteria in the colon. The release of 5-ASA from the coated tablets occurred linearly as a function of time. Drug release depended on the composition of the mixed film as well as the ratio of Eudragit RS to PGA or its salts. The highest drug release from the coated tablets of about 40% was obtained when the ratio of Eudragit RS to potassium salt of PGA was 2.5 to 1. Drug release profiles seemed to conform to the mechanism involving the formation of channels in the film caused by dissolution of PGA salts. Channel formation was, in most cases, activated by the presence of pectinolytic enzymes showing that the PGA in the mixed film was subjected to enzymic breakdown. In conclusion, PGA could be used as an addition in Eudragit RS films to control the release of colonic delivery system.