

Promising ternary dry powder inhaler formulations of cromolyn Sodium: formulation and in vitro – in vivo evaluation

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Abstract

Glucose monohydrate and sorbitol were evaluated as alternative carriers to α -lactose monohydrate in dry powder inhalations. Cromolyn sodium (CS) - carrier binary formulae were prepared and tested in vitro by aerosolization via a twin stage impinger using three types of inhaler devices; Spinhaler®, Aerolizer® and Handihaler®. Glucose monohydrate and sorbitol containing formulae that were inhaled via a Handihaler® showed significantly higher drug fine particle fractions ($P < 0.001$) than that of the same formulae aerosolized via other devices. Upon storage of the prepared formulae under uncontrolled humidity, that may be encountered during storage and use, marked reductions in these fractions were observed. Incorporation of an optimum Aerosil® 200 concentration, as a ternary component, minimized this effect. A urinary excretion pharmacokinetic method was used to evaluate the bioavailability of the selected ternary formulae, inhaled via a Handihaler®, relative to the marketed Intal® Spincaps®, inhaled via a Spinhaler®. It was found that the relative bioavailability percentages of the developed formulae were more than twice that of the marketed one suggesting possible future utilization of these more effective ternary formulae using the more efficient Handihaler® inhaler device.

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