ABSTRACT

Hydrocortisone sodium succinate is the most common and useful antiinflammatory drug of the adrenocortical steroids category. It is most widely used in the treatment of asthma, endocrine disorders, dermatological disorders, allergic states, etc.

The objective of the present study was to prepare FDTs containing hydrocortisone sodium succinate using various superdisintegrants such as crospovidone, croscarmellose sodium and sodium starch glycolate by direct compression method in different concentrations. The simplex lattice design was applied to evaluate the effect of single or mixture of the above superdisintegrants. The superdisintegrants such as crospovidone, croscarmellose sodium and sodium starch glycolate were considered as independent variables. The final blend was evaluated for Bulk density, Tapped density, Carr's index, Angle of repose and Moisture content. The prepared FDTs were evaluated for appearance, hardness, friability, in vitro disintegrating time, wetting time, water absorption ratio, drug content, in vitro drug release studies and *in vitro* drug diffusion study using pig buccal mucosa. Among the formulations; F2 showed wetting time (46.5 \pm 0.42 s), minimum disintegration time $(15.3 \pm 0.51 \text{ s})$, in vitro dissolution study (98 % release in 7 min.), and in vitro diffusion study (98 % in 5 min.). FT-IR studies revealed the absence of drug polymer interaction. Short term accelerated and intermediate stability studies indicated no significant changes in hardness, friability, in vitro disintegration time, drug content and in vitro drug release studies.

Keywords: FDTs; Hydrocortisone sodium succinate; Asthma; Best formulation; Simplex lattice design.