

ABSTRACT

Bupirone Hydrochloride is used in the treatment of anxiety. It has a short half life and low oral bioavailability of 5%. Therefore, the purpose of this research was to develop unidirectional Bucco-adhesive films of Bupirone Hydrochloride by solvent casting technique using 3^2 full factorial designs. HPMC K15M and Eudragit RL-100 were used as polymers in different proportion. Polyethylene glycol 400 was used as plasticizer and Sodium lauryl sulphate was used as permeation enhancer in different concentration. The physicochemical compatibility of the drug and the polymers was studied by FT-IR spectroscopy. The results suggested no physicochemical incompatibility between the drug and the polymers. In 3^2 full factorial designs, total amount of polymer (X_1) and percentage of HPMC K15M (X_2) was kept as a independent variables. Afterwards, statistically optimization process was carried out and two optimized formulation (OF1 and OF2) was developed. The results of optimization formulation showed greater degree of % similarity with predicted values. Stability studies of two optimized formulations were carried out at room temperature as per ICH Q1C guidelines. The stability studies showed that there was no significant change found in physico-chemical properties, *in-vitro* release and *ex-vivo* diffusion studies.

KEYWORDS: Bupirone Hydrochloride, Buccal films, Buccal Drug Delivery System, Optimization formulation, Full Factorial Design, Stability studies.