Formulation and evaluation of Sublingual thin film for management of Migraine

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Abstract

In the present study, an attempt was made to develop fast dissolving sublingual thin film of Almotriptan malate by solvent casting method intended for treatment of migraine and selection of most satisfactory formulation by *in vitro* evaluation. Drug-excipients compatibility study was carried out using Fourier Transform Infrared spectroscopy (FTIR) which shows that drug and excipients were compatible to each other. Sublingual thin film of Almotriptan malate containing Hydroxy Propyl Methylcellulose E5LV and glycerin were developed by solvent casting method. An optimized formulation was having excellent appearance, transparency, % elongation, tensile strength, folding endurance and in vitro disintegrating time by releasing more than 98% drug within 7 minutes in pH 6.8 phosphate buffer. The *in vitro* disintegrating time was found to be less than 60 sec and it was found that no residue remained after disintegration in the media. Film also showed pleasant taste. Glycerin (40 % w/w) was used as the plasticizer which gave good elasticity to the film. Stability studies of an optimized batch showed no significant change in appearance, elasticity, folding endurance and *in vitro* drug release after storage at 40 ±2 ^{o}C and 75±5% RH and 30±2^{o}C and 65±5 % RH for period of two months. This approach suggested that the fast dissolving sublingual thin film of Almotriptan malate using Hydroxy Propyl Methylcellulose E5LV and glycerin gives quick onset of action in around 60 seconds and improved patient complience in management of migraine.

Key words : Sublingual thin film, solvent casting method, Almotriptan malate, Acute migraine, quick onset of action.