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Formulation and Optimization of Zolmitriptan Oral Fast Dissolving Films

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Abstract : The present research work deals with development and optimization of oral fast dissolving films of zolmitriptan to improve bioavailability and patient compliance.It is anti-migraine drug which has oral bioavailability of 45% due to hepatic firstpass metabolism. Oral fast dissolving films of zolmitriptan were prepared by solvent casting method using HPMC E-5 as a film forming polymer, propylene glycol as a plasticizer, sodium starch glycolate as a superdisintegrant and aspartame isadded as sweetener. Theprepared film characterised by FTIR showed no incompatibility between drug and polymer. A 2^3 factorial design is employed for the optimization of formulation considering concentration of polymer, plasticizer and superdisintegrant as independent variables with drug release, disintegration time, folding endurance as dependent variables. The formulations F1-F8 are made by varying the levels of independent variables and evaluated for disintegration time, dissolution rate and foldingendurance. The results are treated by DesignExpert softwareto optimise the oral fast dissolving film. Theoptimised film isanalysed by X-ray diffraction shows crystalline to amorphous transformation of drug and DSC thermogram shows a broad peak further conforms the amorphous nature of drug. It was found that enhancing the polymer and plasticizer concentrations shows negative effect on disintegration time and drug release. But when the concentration of superdisintegrant was increased it had a positive effect on drug release and disintegration time. From the results obtained the optimized formulation was prepared with 4% of HPMC E5, 1.5% of propylene glycol and 4%of sodium starch glycolate showed disintegration time 10 sec, drug release 93.15% and folding endurance of 260 times.

Key words : Zolmitriptan, Hydroxyl Propyl Methyl Cellulose, Propylene glycol, Sodium starch glycolate, Aspartame.

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