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Orodispersible films of a polymorphic poorly soluble drug: Effect of casting solvent, film forming agent and solubilizer

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In the current work, a full factorial experimental design was utilized to formulate piroxicam into orodispersible films while investigating the effects of some formulation factors on the properties of the resulting films. These factors were: (1) The casting solvent: Water and acetone/water mixture, (2) the film forming agent: HPMC K4M and Na-alginate and (3) the solubilization system: No solubilizer, L-arginine, poloxamer and L-arginine/poloxamer mixture. 16 formulation runs were prepared by solvent casting method to obtain 10 mg piroxicam dosage units. Drug particle size in the prepared formulations and dissolution efficiency at 30 minutes were selected as responses variables. Additionally, the prepared films from each formulation were evaluated for other characters as drug content, thickness, residual water, etc. A selected formulation was then evaluated for its *in vivo* disintegration, palatability and stability. Utilizing acetone in the casting solution, Na-alginate as film forming agent or both of them resulted in formation films with larger drug particles and slower dissolution. Combined use of L-arginine and poloxamer showed better drug dissolution than using each alone. HPMC was more favorable than Na-alginate regarding mechanical properties and moisture absorption. Films from the selected formulation showed fast *in vivo* disintegration and acceptable palatability. These films were stable for six months under accelerated storage conditions.

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