IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 2, June 2024

Formulation and Evaluation of Oral Thin Film

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Abstract: *The aim of this study was to develop a fast-releasing oral polymeric thin film, prepared by solvent casting method, with good mechanical properties, instant disintegration and dissolution. Phenylephrine hydrochloride, a sympathomimetics drug belonging to BCS class I was used for oral thin film preparation. The formulations from the preliminary trial were analyzed which was applied to optimize the type of polymers (Sodium alginate, HPMC & cross povidone), concentration of polymers, plasticizer (Glycerol, Propylene Glycol,), surfactant (Sodium lauryl sulfate) and sweetener (sorbitol). The resultant films were evaluated for thickness, folding endurance, drug content, Surface pH, in vitro disintegration time, in vitro dissolution studies. The in vitro release study revealed that B4 formulation showed maximum release in 240 sec. For B4 Formulation In-vitro disintegration time was found to be 30sec, Thickness was 0.24mm, Folding endurance 78 and Swelling Index was 14.64. The B4 formulation was found to be stable as there was no drastic change in the Physico-chemical properties of the films. Thus, conclusion can be made that stable oral disintegrating film of Phenylephrine Hydrochloride has been developed. B4 formulation showed highest cumulative percentage drug release of 98.75% obtained during In vitro drug release studies after 240 sec. Based upon the in vitro dissolution data the B4 formulation was concluded as optimized formulation.*

Keywords: Phenylephrine hydrochloride, sodium alginate, oral polymeric thin film, solvent casting technique, HPMC, In vitro drug release studies.