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Formulation and Evaluation of Trifluoperazine Hydrochloride Orodispersible Tablets

A Thesis

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BY

Ibtihal Abdulkadhim Dakhil

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Supervised by

Assistant Professor

Dr.Nidhal Khazaal Maraie

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Abstract

Trifluoperazine hydrochloride (TFP) is an antipsychotic drug; it is widely used in the treatment of psychotic conditions, acute and chronic schizophrenia. In lower doses it is used in management of nausea and vomiting.

In the present work trifluoperazine hydrochloride was prepared as orodispersible tablets (ODTs) to enhance the disintegration and dissolution of trifluoperazine hydrochloride which may improve the bioavailability of the drug through reducing first pass effect and to make easier administration for geriatric, mentally ill and dysphagic patients.

Several formulas of TFP ODTs were made by direct compression and wet granulation method using various types of superdisintegrants sodium starch glycolate (SSG), croscarmellose sodium (CCS), indion 4104 and crospovidone (CP).

Many variables were included such as effect of subliming agents (camphor, menthol and ammonium bicarbonate) at different concentrations, glycine as disintegration enhancer at different concentrations, effervescent base in different ratios in addition to the use of different types of diluents, the properties of ODTs had been studied.

The prepared formulas were evaluated for flow properties, hardness, friability, *in-vitro* disintegration time, *in-vivo* disintegration time, drug content, wetting time and *in-vitro* drug release.

Formulas were prepared by direct compression and wet granulation methods showed acceptable flow characters and all formulas exhibited good mechanical strength except for those containing subliming agents.

Crospovidone containing formula showed the shortest disintegration time ($p<0.05$) among other superdisintigrants and fast drug release.

Among all the prepared formulas, Formula (F9) which prepared by direct compression method (containing 10% w/w crospovidone, 20%w/w microcrystalline cellulose 20%w/w, aspartame, talc, mg-stearate and mannitol) was selected as the optimum formula, since it gave the best results of evaluation were the weight variation within the pharmacopeia limit (±7.5%), hardness (3.8kg/cm^2), friability (0.73%), *in-vitro* disintegration time (14.6 sec), *in-vivo* disintegration time (19 sec), wetting time (9.3 sec) drug release profile (the time required for 80% of the drug to be released ($T_{80\%}$) and percent drug dissolved in 2 min ($\%D_{2min}$) were 1.93 min and 82.88% respectively) .

The drug-excipients compatibility study indicated that no interaction between the drug and the excipients of the optimum formula (F9). The stability study of the optimum formula (F9) was done and the expiration date was calculated and found to be 2.5 years.

The overall results suggested that the prepared formula of TFP (F9) could be utilized as ODTs for oral administration.