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FORMULATION AND EVALUATION OF CITALOPRAM HYDROCHLORIDE LOZENGES

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ABSTRACT

Despite the presence of many dosage forms available in the market, lozenges possess a significant role, as they are suitable for patients with swallowing difficulty. This study focuses on the formulation and evaluation of citalopram hydrochloride lozenges as an alternate dosage form, especially for geriatric patients. The lozenge formulation is designed to release citalopram hydrochloride slowly in the mouth. The main advantage of the lozenges over conventional tablets is that they reduce gastric irritation and avoid first-pass metabolism. These lozenges were made using polyethylene glycol as a base and glycerin as a solvent. The process involves melting polyethylene glycol at 50-55°C. The Citalopram HCl was mixed with glycerin to form a smooth paste, then added into the melted base with continuous stirring, then cooled and poured into lozenge molds. The prepared lozenges were evaluated for organoleptic properties, melting point, weight variation, hardness, friability, disintegration time, and in vitro drug release. All evaluation parameters were within an acceptable range.

KEYWORDS: Citalopram Hydrochloride, Lozenges, Geriatric Drug Delivery, Swallowing Difficulty, Polyethylene Glycol Base, Controlled Release.

INTRODUCTION

Lozenges are solid dosage forms that are intended to release the drug in the mouth. They usually contain a sweet base to mask the taste. These are used by the patients who have swallowing difficulty. Mainly used by geriatric and pediatric patients. Based on the patient's

needs, lozenges are prepared, which are used in the treatment of various throat infections and provide a mild analgesic effect.[1] They are prepared by the process of dissolving the drug in a polyethylene glycol base.[2] Citalopram hydrochloride is an antidepressant that belongs to the class of selective serotonin reuptake inhibitors. It is used in the treatment of depression, panic disorder, and anxiety disorder. It works by increasing serotonin levels in the brain, which in turn improve mood.[3] The present study focuses on formulation and evaluation of Citalopram HCl lozenges for content uniformity, physicochemical properties, and stability.

MATERIALS AND METHODS

MATERIALS

Citalopram hydrochloride, glycerine, polyethylene glycol.[2]

METHODS

Determination of melting point

Filled the capillary tube with powdered sample by pressing the open end into the sample. The melting point apparatus was switched on, and the capillary tube was inserted into the melting point apparatus. The sample was watched through the eyepiece to determine the temperature at which it started melting, and this was noted down.[4]

Preparation of Citalopram HCl lozenges

Formula

Ingredients	Quantity for 1 lozenge	Quantity for 20 lozenges	Category
Citalopram HCl	0.22	4.4	Selective serotonin reuptake inhibitor
Polyethylene glycol(PEG)	0.5	10	Base
Glycerine	Upto 1	Upto 20	Solvent

PROCEDURE

Determined the required quantities of Citalopram hydrochloride powder and PEG. Gently melt the PEG troche base at 50°C to 55°C until liquified. Separately, mix the weighed Citalopram HCl powder with a small amount of glycerin to form a smooth paste. Added the paste to the melted PEG base while mixing continuously to ensure even distribution. Cooled the mixture, then poured it into appropriate lozenge molds.[2]

Fig. 1: Preparation of Citalopram HCl lozenges.

EVALUATION TESTS

Organoleptic test

Physical evaluation of Citalopram HCl, like color and odor, was done.[5]

Weight variation test

Weight variation is used to evaluate the uniformity of lozenges in the batch. Weighed 15 lozenges from the prepared batch of the formulation, calculated the average weight, and compared the individual weight of the lozenges to the average.[6]

Percentage deviation = (Average Weight - Individual Weight) / Average Weight x 100.

Hardness test

Lozenges' hardness measures the resistance to breakage during storage and transportation. The Monsanto hardness tester is used to determine the hardness of the lozenges, and the force required to break them was recorded. In terms of kg/cm², the hardness was measured. The process was repeated for each lozenge, and the average value was calculated.[6]

Friability test

The friability of the lozenges was evaluated with the help of a Roche friabilator. The prepared lozenges are weighed first and placed in a friabilator and rotated at 25 rpm for 4 minutes. After 4 minutes, the lozenges were removed, dedusted, and reweighed.[6]

The percentage deviation of friability is calculated using the following formula:

% Deviation of friability = [(W0 - Wf)/W0] × 100.

Disintegration test

The disintegration test was done, and the disintegration time of lozenges from each batch was determined with the help of the USP disintegration equipment. At 37°C, disintegration time was measured in a phosphate buffer pH 6.4.[7]

In Vitro Dissolution time

Filled the dissolution vessels with 900 mL of phosphate buffer, pH 6.8, and maintained temperature. Placed one Citalopram HCl lozenge in each vessel. Operated the apparatus at 50 rpm. Withdraw 5 mL of sample at 5, 10, 15, 20, and 30 minutes. Replaced each withdrawn sample with an equal volume of fresh medium maintained at the same temperature. Filtered the samples using a membrane filter. Measured absorbance using a UV-visible spectrophotometer at 239 nm. Calculated cumulative percentage of drug dissolved using a calibration curve of Citalopram HCl.[8][6]

RESULTS AND DISSCUSSION

Organoleptic examination

Parameter	Result
shape	Spherical
odour	odourless
colour	White

Melting point

The melting point was found to be 185 °C.

Evaluation of citalopram HCl lozenges

Test	Result
Weight variation	± 5%
Hardness test	4.5kg/cm²
Friability test	0.4%
Disintegration test	20 minutes

In Vitro Dissolution Test

S.NO	Time	Absorbance	Dilution factor	Conc=absorbance/slope*100(X)	X/1000Y Conc mg/ml	Cumulative Amount Y*900=Z	% Release Z/dose*100
1	0	0	0	0	0	0	0
2	5	0.457	10	20.77	0.0207	18.63	93.15%
3	10	0.34	10	15.45	0.0154	13.86	69.3%
4	15	0.33	10	15	0.015	13.5	67.5%
5	20	0.39	10	17.72	0.0177	15.9	79.5%
6	25	0.45	10	20.45	0.0204	18.36	91.8%
7	30	0.52	10	23.63	0.0236	21.24	106.2%

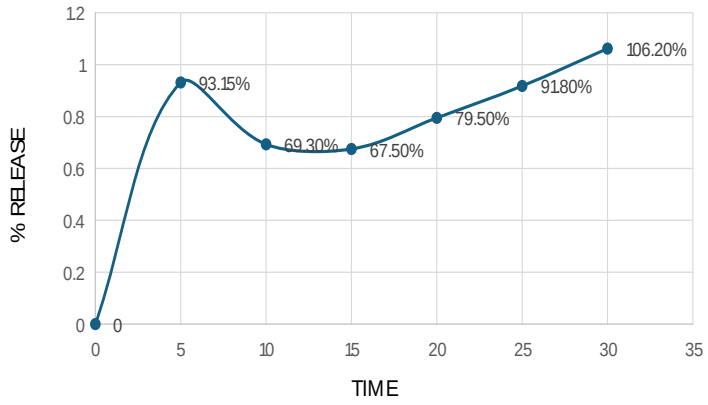

Fig. 2: Dissolution profile of Citalopram HCl lozenge.

DISCUSSION

The prepared lozenges were found to be white in color, spherical in shape, and odorless, which indicates that they are in acceptable condition. The melting point was found to be 185°C, which indicates that the drug is pure. The weight variation of prepared lozenges was within the limit of ± 5%. The hardness of the lozenge was found to be 4.5 kg/cm², which comes under the acceptable range. The friability was observed to be 0.4%, which comes under the acceptable limit of 1%. The disintegration time was found to be 20 minutes, which is within the limit. The dissolution study showed that the drug release increased with time; the maximum drug release was observed at 30 minutes. We have observed a slight variation in the intermediate values due to sampling or experimental handling.

CONCLUSION

The present study focused on the formulation and evaluation of Citalopram HCl lozenges using polyethylene glycol as a base. The prepared lozenges exhibit acceptable appearance, hardness, friability, and uniform weight variation. The disintegration time was found to be appropriate for a lozenge formulation, ensuring slow dissolution in the oral cavity for a prolonged period of time. In the dissolution study, we observed the maximum drug release at 30 minutes; hence, the results confirm that Citalopram HCl can be formulated into lozenges and can be used by the patients who have swallowing difficulty.

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