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DEVELOPMENT AND EVALUATION OF PARACETAMOL LOZENGES

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ABSTRACT

Oral route was very common route of drug administration because ease of administration, flexibility in formulation, Paracetamol has antipyretic and analgesic properties, it was used for management of fever and headache. Some people having difficulty in swallowing the tablets and people having throat infection cannot take medicines orally, so there was ademand for solid dosage form that was easy to administer such as medicated lozenges. Paracetamol lozenges were prepared for gradual release of medicament to get relief from fever and pain. The sugar-based Paracetamol medicated lozenges were prepared for thepatient who have difficulty in swallowing the tablet and people who have throat infection. The medicated Paracetamol lozenges were evaluated for various physiochemical parameters like Friability, weight variation test, hardness test, dissolution test, and disintegration test**.** Paracetamol lozenges were found to be best alternative compared to Paracetamol tablet for the patients having difficulty in swallowing.

KEYWORDS: Paracetamol, Lozenges, Friability, Dissolution Test, Citric Acid, Hardness Test.

INTRODUCTION

Paracetamol drug belongs to the class of NSAID, it was mainly used to relieve headache and fever and is over-the-counter drug. Paracetamol is suitable to be used orally in tablet form but overdosing may cause damage the liver.[1] When Paracetamol tablet is taken orally itundergo

first pass metabolism but when Paracetamol lozenges will not undergo first pass metabolism. Medicated Paracetamol lozenges have many advantages over the Paracetamol tablet. The larger dose can be easily administered in the lozenges. People who have fever and headache but difficulty in swallowing or throat infection the tablet for this type of patients, medicated Paracetamol lozenges are best alternative compared to Paracetamol tablet. The Paracetamol lozenges will also be helpful for children. These medicated lozenges held in the mouth for some time so that drug gets dissolved, absorbed and enter into systemic circulation. Thus, in the present study efforts were made to prepare and evaluate paracetamol lozenges.

MATERIALS

Paracetamol was obtained from Sigma Aldrich, Sucrose was obtained from the local store, Water was taken from Water purifier, Xylitol was obtained from Prado Chemical, Citric acid was obtained from siyaram chemicals, Aspartame was obtained from local store.

METHOD

Formulation Development: The syrup for medicated lozenges was prepared using sugar and water and the drug was added to it and have mixed properly then xylitol and aspartame were added to it so that xylitol and an aspartame should mask the taste of Paracetamol drug.[2] Briefly, sufficient quantity of sugar and water were added to the beaker, then boiled the mixture on a water bath till the mixture turned into viscous liquid. Then, xylitol, citric acid and aspartame were added respectively, to the viscous liquid and mixed well. Lastly, Paracetamol was added and mixed it properly. The viscous mixture was then poured into the silicon mould and allowed to dry the mixture. After complete drying medicated Paracetamol lozenges were collected from the mould.[3,4] Table 1 represents the ingredients and quantity used in formulation.

Table I: Formulation of medicated paracetamol lozenges.

Ingredients	F1	F2	F3	F4	F5	F6	Uses
Sugar	30 g	30g	30g	30g	30g	30g	Sweeteningagent
Water	5ml	5ml	5ml	5ml	5ml	5ml	Diluent
Xylitol	10mg	15mg	20mg	25mg	30mg	35mg	Sugar substitute
Citric acid	1mg	1.2mg	1.4mg	1.6mg	1.8mg	2mg	Flavoringagent
Aspartame	15mg	20mg	25mg	30mg	35mg	40mg	Sweeteningagent
Paracetamol	125mg	125mg	125mg	125mg	125mg	125mg	Relive from fever and headache

Evaluation of paracetamol lozenges[5,6]

Weight variation: Twenty lozenges were individually weighed and the individual weight of each lozenge was compared with the average weight of twenty lozenges.

Friability test: Initial weight of lozenges was taken then after hundred rotations of lozenges again weight was taken then the percentage friability of lozenges was calculated.

Dissolution test: Prepared 1000ml of 7.2 PH of phosphate buffer medium for dissolution test and pour 900ml in jar and put one medicated lozenges in same jar and withdrawn 5ml of sample from the same jar after every 30 minutes up to 3 hour, then absorbance was checked in UV-spectroscopy

Disintegration test: The outer jar of disintegration apparatus filled with phosphate buffer media and 4 lozenges were put in the beaker of disintegration apparatus and noted the time taken by lozenges to disintegrate completely

Length and diameter: Length and diameter of Paracetamol lozenges were measured using Vernier caliper. The lozenges were kept in the center of the vernier caliper and noted the length and diameter of lozenges

Hardness test: The hardness test of each lozenge was measured by using hardness tester

RESULTS AND DISCUSSION

These medicated paracetamol lozenges showed elegant physical appearance. The weight variation test of medicated paracetamol lozenges was in the range of 0.51 to 0.52, and the percentage friability was found to be zero, the time taken by medicated paracetamol lozenges to disintegrated completely was in the range of 6min and 2sec to 6min 38sec, The dissolution test was carried out for all the formulations. The percent release of all the formulations were as; F1-84.12± 1.2%, F2-82. ± 1.5%, F3-83± 1.8%, F4-83± 1.6%, F5-84± 1.0%, and F6-83 ± 1.7% respectively at end of 60 mins. The length of medicated lozengeswas in the range of 3.3cm to 3.6cm and the average diameter of each lozenges was found tobe in the range of 3cms to 3.2cms. Prepared medicated paracetamol lozenges had good hardness and the hardness was found in the range of 8 to 9. All other parameters were within the acceptable range. Thus, by observing the above results we can conclude that the medicated paracetamol lozenges passed physiochemical tests.

Table-II: Physiochemical parameters of medicaredparacetamol lozenges.[7,8]

Parameter	F1	F2	F3	F4	F5	F6
Weight variation(gm)	0.51	0.52	0.51	0.52	0.52	0.51
Friability	0	0	0	0	0	0
Disintegration	6min 38sec	6min 12sec	6min 2sec	6min 32sec	6min 28sec	6min 2sec
Length(cm)	3.3	3.5	3.5	3.6	3.4	3.5
Diameter(cms)	3.1	3	3.1	3.1	3	3.2
Hardness	8	9	8	8	9	8

CONCLUSION

From above data it is concluded that excipients present in the lozenges was compatible with drug, and these lozenges are elegant with sufficient hardness, friability, and dissolution. As, the lozenges bypasses the first pass metabolism, the side effects associated with conventional tablets can be overcome. Thus, the Paracetamol lozenges were found to be best alternative compared to Paracetamol tablet for the patients having difficulty in swallowing with reduced side effects and patient compliance.

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