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Development and Evaluation of Medicated Chewing Gum Formulations of Ondansetron

Kapil Kumar *, Adesh, Deepak Teotia, Ikram

Department of Pharmaceutics, Global Institute of Pharmaceutical Education and Research, Kashipur- 244713, Uttarakhand, India

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*Address for Correspondence:

Kapil Kumar, Department of Pharmaceutics, Global Institute of Pharmaceutical Education and Research, Kashipur- 244713, Uttarakhand, India

ORCID ID: <https://orcid.org/0000-0003-0481-7109>

INTRODUCTION:

In present scenario oral route is preferable way for the self-medication due to enhanced patient convenience and compliance.

There are so many benefits associated with this route like no pain, ease to use versatility, and patient compliance. As compared to parenteral formulations there are economical as there is no need of the sterilization conditions. Many researchers are working on different dosage form development for the purpose of oral administration. The main emphasis is at the development of NDDS (novel drug delivery systems) and finally for the improvement of the patient compliance.

As far as different dosage forms are concerned oral cavity is acceptable; mucosa is relatively permeable with sufficient supply of the blood and it is easy to tolerate¹⁻⁵.

Oral dosage forms possess a limitation that there is need of water to swallow the formulations, problem arises during travelling or in the condition whenever there is no water available for the administration. There are so many patients having problem in swallowing like in paediatric and geriatric patients. In all these conditions, chewing gum formulations can offer an alternate to this formulations⁶⁻⁸.

Chewing gum is a soft, cohesive substance designed to be chewed without being swallowed.

Abstract

The objective of the present study was formulation and evaluation of medicated chewing gum formulations of Ondansetron. Four medicated chewing gum formulations of Ondansetron were prepared by direct compression mould method. Formulations were characterized for physical evaluation, weight variation, stickiness, hardness/plasticity, *in vitro* drug release, and drug release study. All the formulations gave satisfactory results in physical evaluation, weight variation, stickiness, and hardness. The formulation of batch F4 showed best *in vitro* drug release which is 60.68% in 25 min and it is also more accepted by the people. In conclusion, prepared formulations can be cost-effective product and also showed better compliance and increase in bioavailability.

Keywords: Chewing gum, Ondansetron, direct compression mould method, solid oral delivery systems

So, these formulations are helpful for those who have difficulty to swallow and do not take medicines according to prescription^{6,7}.

Ondansetron HCl is a drug used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, or surgery. It is also effective for treating gastroenteritis. It can be given by mouth or by injection into a muscle or into a vein⁹⁻¹¹.

Objective of the work is to prevent inherent drawbacks associated with conventional tablets such as risk of choking, bitter taste and difficult in swallowing by formulating orally disintegrating tablets of Ondansetron HCl thereby providing faster disintegration and rapid release, bypassing first pass effect, improved patient compliance and therapeutic effectiveness¹².

The present work was carried out to formulate orally disintegrating tablets of Ondansetron hydrochloride and to evaluate the tablets for various parameters.

MATERIALS AND METHODS:

Ondansetron, Poly Vinyl acetate, Betacyclodextrin were obtained from Agron Pharmaceuticals, Kashipur, India (Gift sample). Polyethylene glycol and Poly Vinyl alcohol were obtained from Pharma Fabrikon, Madurai India. All other ingredients used were of analytical grade.

Preparation:

Chewing gum formulations were prepared by the means of Melting method. It was based on the melting of gum base in a china dish, to this adds other ingredients and mixed well and rolled in CaCO_3 powder, where chewing gum is cut into required size and shape. Basic advantage of the melting technique was it is simple and had a low cost.

Different 4 formulations of Ondansetron chewing gums (F1, F2, F3, F4, were prepared by using different polymers like (PEG-4000, PVA, Cross povidone, β -CD) at different concentrations were used^{13,14}.

Characterization:

Weight Variation

Randomly selected formulations were taken and weighed. The batch was considered pass, if not more than 2 formulations were showing deviated results¹⁵.

Friability

Roches friabilator was used for the friability estimation of the Chewing gums. The chewing gums were placed into the apparatus for four minutes, which was rotating at the speed of 25 revolutions/min. Then the chewing gum was removed and de dusted and weighed. The Percentage loss in weight was calculated and taken as a measure of friability. Ideally there should not be more than 1 % variation of weight loss¹⁶.

Stickiness

On plain surface, medicated chewing gum was placed; it is subjected to collide with Teflon hammer with mass of 250 g for a period of 10 min. Hammering frequency was 30/min. After specified time, amount of mass stick to hammer was observed and reported¹⁷.

Test for hardness

There is no one reported method for the determination of hardness; hence, it was decided to use Pfizer type hardness tester for the determination of hardness/plasticity of all MCG formulations¹⁸.

Determination of drug content:

Drug content was measured by the means of UV Spectrophotometer. The results suggest that the process

Table 2: Evaluation parameters of prepared chewing gum formulations.

S.NO.	Formulation Code	Colour	Texture	Stickiness
1.	F1	Light Orange	Good	NIL
2.	F2	Light Orange	Good	NIL
3.	F3	Light Orange	Hard	NIL
4.	F4	Light Orange	Good	NIL

All chewing gums were elegant in appearance and non-sticky. This indicates the formulations are suitable for the packaging and storage purpose. The thickness for the best formulation was in the range of 3.7 ± 0.03 to 4.2 ± 0.06 . The results indicated a uniform particle size distribution and no deformities. The hardness for the best formulation was found to be in the range of 2.1 ± 0.24 to 2.8 ± 0.16 . All formulations has passed weight variation test. The results indicated that the tablets of

employed to prepare the chewing gum shown distribution of drug¹⁹.

In-vitro drug release

In vitro study was performed on modified dissolution apparatus by taking a medicated chewing gum in the receptor compartment and then it was subjected for a number of compression cycle of 40 to 50 times per minute. This study was carried out in pH 6.8 for 25 minutes. Samples were collected at a regular interval and was evaluated by UV spectroscopy^{20,21}.

Table 1: Composition of chewing gum formulations

Ingredients	F1	F2	F3	F4
Ondansetron	400	400	400	400
Gum base	200	200	200	200
Glycerol	10	15	20	25
Sucrose	100	100	100	100
Calcium Carbonate	35	35	35	35
Liquid glucose	45	45	45	45
Mannitol	202	197	192	187
Aspartame	5	5	5	5
Flavour	3	3	3	3

RESULTS:

In present study total 4 chewing gum formulations were developed. Chewing gums formulations were analyzed for different parameters like hardness, drug content uniformity, % drug release.

formulation have good hardness, which in turn protects from mechanical damage. Friability was found in the range of 0.62 ± 0.08 to 0.71 ± 0.07 . The best formulation chewing gums passes weight variation test and the weight variation was within the pharmacopoeia limits of \pm of the weight. The results indicated that all chewing gums formulation have uniform weight.

Table 3: Properties of the chewing gum formulations

Formulation Code	Thickness (mm) \pm SD	Weight variation (gm)	Drug content in percentage \pm SD	Hardness (kg/cm ²)	Friability \pm SD
F1	4.2 \pm 0.06	1.004	90.82 \pm 0.63	2.1 \pm 0.24	0.71 \pm 0.07
F2	4.1 \pm 0.10	1.003	93.33 \pm 0.62	2.5 \pm 0.11	0.68 \pm 0.14
F3	3.9 \pm 0.01	1.006	95.58 \pm 0.76	2.8 \pm 0.16	0.62 \pm 0.08
F4	3.7 \pm 0.03	1.007	94.49 \pm 0.89	2.6 \pm 0.25	0.66 \pm 0.09

The maximum drug release of 60.68% was shown by the formulations of batch F4, while minimum release 22.47% was shown by the formulations of batch F1.

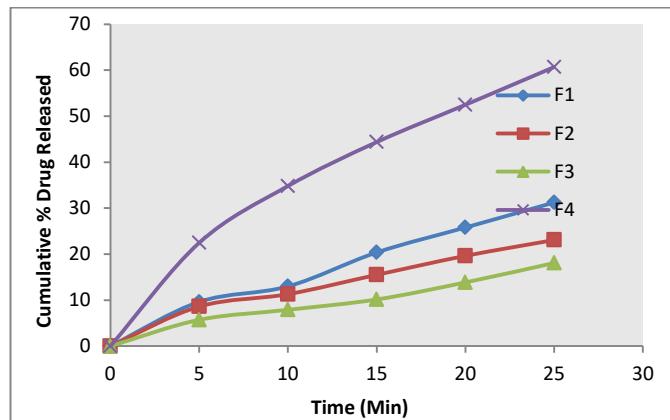


Figure 1: Percent drug release from chewing gum formulations

CONCLUSION:

Present study concluded that Medicated chewing gum of Ondansetron can be successfully prepared by melting method using different concentrations of plasticizer and synthetic gum base. On the basis of different evaluation parameters, formulation F1 was the optimized formulations are kept for stability studies. Thus, it's the better option to prepare Ondansetron into a medicated chewing gum to achieve better patient compliance and improved drug release.

As far limitation of the study is concerned, there is need of in-vivo testing of prepared formulations to prove the efficacy of the prepared formulations.

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