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EFFICACY OF PLANTAGO OVATA MUCILAGE USED ON RAPIMELTS TABLET OF METACLOPRAMIDE HCL

Abhinav kumar Tripathi*, Dr. Hemendra Gautam
Shri Venkateshwara University, Gajraula (UP)
Conflicts of Interest: Nil
Corresponding author: Abhinav Kumar Tripathi, Research Scholer, Shri Venkateshwara University, Gajraula (UP)

ABSTRACT

To achieve taste masking of drug. prepare preliminary trial batches of rapimelts using plantago ovata mucilage as natural superdisintegrant and crosspovidone as synthetic superdisintegrant by direct compression method. Rapimelts tablet of metoclopramide Hcl tablets by determination of range of technological parameters. Dissolution profile suggested that tablet prepared with Plantago ovate mucilage were capable of releasing up to 90 % drug within 15 minutes in phosphate buffer 6.8 pH, by an appropriate combination of excipients it is thus possible to obtain Rapimelts tablet of metoclopramide Hcl tablets using simple and conventional technique.different ratio of drug and polymer. To Evaluate the drug polymer complex and finally which polymer and ratio of drug and polymer is better to formulate final formulation. To achieve taste masking of drug. To prepare preliminary trial batches of rapimelts using plantago ovata mucilage as natural superdisintegrant and crosspovidone as synthetic superdisintegrant by direct compression method. To evaluate the prepared rapimelts for various properties like friability, hardness, wetting time, water absorption ratio, disintegration time, drug content, drug etc. Identifying the key variables and their levels for applying factorial design and to optimize one formulation. To evaluate the final batches and find out the optimized batch based on statistical optimization using experimental design. To compare the optimized formulation with marketed preparation. To carry out stability studies of optimized batch as per ICH guidelines. The aim of the present investigation was to Formulate, designed, and evaluate plant agoovata mucilage used as a natural superdisintegrant was to developed and optimized rapimelts containing Metoclopramide HCL..

Keywords: Metoclopramide, rapimelts

Introduction

Dosage forms are the means by which drug molecules are delivered to sites of action within the body[1].

Tablets and capsules are the most popular and frequently dispensed medication dosage form because they are convenient for self-administration and easily handled by the patient; however, there are many other different dosage forms available for patients.

RAPIMELT

The US Food and Drug Administration Centre for Drug Evaluation and Research

(CDER) defines, in the 'Orange Book', a rapimelt as **"A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue".**

The significance of these dosage forms is highlighted by the adoption of the term, "Rapimelt", by the European Pharmacopoeia which describes it as a **tablet that can be placed in oral cavity where it disintegrate rapidly before swallowing.** Rapimelts are distinguished from conventional sublingual tablets, buccal tablets, and lozenges, which require more than a minute to disintegrate in oral cavity. In the literature, rapimelts are also called as Fast disintegrating, fast dissolving, mouth dissolving, rapid dissolve, quick disintegrating, orally disintegrating, fast melts, Orodispersible, melt in mouth, quick dissolving, porous tablets or effervescent drug absorption system. But, the function and concept of all these dosage forms are similar. It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A rapimelt usually disintegrate in the oral cavity within 15 s to 3 min. Most of the

rapimelts include certain superdisintegrants and taste masking agents.

This mode of administration was initially expected to be beneficial to paediatric and geriatric patients, to people with conditions related to impair swallowing, and for treatment of patients when compliance may be difficult. The main purpose of this work is only to improve patient compliance without compromising the therapeutic efficacy[9,10].

ADVANTAGES

- Easy to administer to the patient who cannot swallow such as paediatric, geriatric, etc.
- Convenient for administration to travelling patients.
- Excellent mouths feel property produced by use of flavours and sweeteners help to change the perception of "medication as bitter pill"especially in paediatric population.
- Rapimelt tablets leads to quick disintegration and rapid absorption which may produce rapid onset of action.
- Rapimelts offer all the advantages of solid dosage forms and liquid dosage forms.
- Convenience of administration and accurate dosing compared to liquids[11].

DISADVANTAGES

- Effective taste masking technologies should be adopted for bitter taste drugs.
- Degradation of drug can take place in highly enzymatic environment.
- It has relatively small surface area.
- There is risk of choking or swallowing of formulation.
- Rapimelt's exhibit low sensitivity to environment condition such as humidity and

temperature.[11]

- If you are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in Section 6).
- If you have high blood pressure.
- If you have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest.
- If you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).
- If you are at the same time taking some other medicines for migraine (e.g. ergotamine or ergot-type medicines like dihydroergotamine and methysergide) or other triptan medicines for migraine. See '**other medicines and Rapimelt**' for further information.

Do not take Rapimelt if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rapimelt.

Materials and Methods

Examination of drug by determining melting point:
Melting point of Metoclopramide HCl was determined by Melting Point Apparatus.
Metoclopramide HCl was filled in capillary tube and capillary tube as well as thermometer was kept in Melting Point Apparatus. The point at which Metoclopramide HCl melts is recorded from thermometer.

Examination of drug by UV spectrophotometer38,39:

U.V. scan of Metoclopramide HCl in following media:

- In phosphate buffer pH 6.8
- In 0.1N HCl pH 1.2

-Resulting solutions of 20 µg/ml in 0.1N HCl pH 1.2 and 20 µg/ml prepared in
-Phosphate buffer pH 6.8 were scanned between 200 nm to 400 nm using Double beam UV-visible spectrophotometer.

Materials

ANALYTICAL METHOD DEVELOPMENT

Standard calibration Plot of Metoclopramide HCl in phosphate buffer pH 6.8 and 0.1N HCl pH 1.2

- **Standard (Stock) solutions**:

An accurately weighed 10 mg of Metoclopramide HCl was dissolved and diluted to 100 ml with phosphate buffer pH 6.8 and 0.1N HCl to produce 100µg/ml stock solutions.

- **Preparation of Sample solutions:**

Different dilution of stock solution were prepared using Phosphate buffer pH 6.8 and 0.1N HCl to obtain solution having concentration 4, 8, 12, 16, 20

µg/ml in both the media and absorbances were measured at obtained λmax of 273nm.

Isolation of Plantago ovata mucilage

The husk of Plantago ovata was powdered and passed through a no. 80 screen. The powder was soaked in distilled water for 24 h and boiled for a few minutes, so that complete gelatinization takes place and dried in an oven at a temperature less than 60°C. After drying gelatinized material was collected, and size reduced.

FORMULATION AND DEVLOPMENT

Preparation of Rapimelts by Direct Compression Technique

Rapimelts of Metoclopramide HCl were prepared by direct compression method according to the formula given in table. All the ingredients were passed through 60 mesh sieve separately. The drug and mannitol were mixed by small portion of both and blended to get a uniform mixture. Rest of the ingredients were weighed and mixed in geometrical proportion with Metoclopramide-Mannitol mixture and tablets were directly compressed using 9 mm sizes flat round punch on 10 stations, B tooling Rotary Tablet Compression Machine.

Preliminary study

- **Taste masking of Metoclopramide HCl by complexing with β-cyclodextrin14 Preparation :**

Solid complexes of Metoclopramide HCl−β-CD were prepared in 1:1, 1:2 and 1:3 molar ratios by kneading methods.

Evaluation of Drug-Polymer Complex

- **% Yield:** It is calculated using following formula

Percentage yield = [Wp/Wt] × 100

Where, Wp= actual weight of taste masked particles obtained and

Wt= total weight of drug + polymer

(metoclopramide HCl and β-cyclodextrin).

B. Evaluation Tests for Rapimelts

- **Pre Compression Evaluation**

Pre compression evaluation studies were carried out for following parameter i.e. Bulk density, Tapped density, Hausner's ratio, Carr's index, Compressibility index. These parameters were evaluated on a laboratory scale for preparation of tablets with good flow properties of powder material.

- **Bulk density (Do)**

It is the ratio of bulk volume to the total mass of the powder taken. It was measured by pouring the weighed powder into a 25 ml graduated cylinder and the volume was noted. It is given by:

- **Do = M/Vo**

Where, 'M' is the mass of powder,

'Vo' is the Bulk Volume of powder; it is expressed in g/ml.

- **Tapped density (Dt)**

It is the ratio of mass of the powder to the tapped volume of the powder. The tapped volume was measured by bulk density apparatus in which the powders were tapped for predetermined number of taps until the volume became constant.

It is given by formula:

- **Dt = M/Vt**

Where, 'M' is the mass of powders

'Vt' is the tapped volume of powders; it is expressed in g/ml.

- **Carr's index**

It is the %compressibility index. It is given by

I = (Dt-Do/Do) x 100

Where, 'Dt' is tapped density

'Do' is bulk density; it is expressed in terms of percentage.

Limit: <16- Excellent flow,

16-20-Good flow,

>20-poor flow.

- **Hausner's ratio**

It is the ratio of tapped density to untapped density. It is given by

H = Dt/Do

Where, 'Dt' is the tapped density of powders

'Do' is the untapped density of powders.

Limit: <1.25- Good flow

1.25-1.5- Fair to Passable

>1.5- Poor flow

Angle of Repose

The angle of internal friction is a measure of internal stress distribution and is the angle at which an applied stress diverges as it passes through the bed. It is the least slope at which a powder will slide down an inclined plane surface. It is denoted by **Θ**. Angle of repose was determined using fixed funnel method.

The blend was poured through funnel fixed at a height of 2cm, until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated using the formula

tan-1 Θ = h/r

The values of angle of repose obtained can be interpreted as follows:

Post Compression Evaluation

- **Weight variation**

As per U.S.P. procedure, 20 tablets were selected randomly from the lot and weighed individually on digital weighing balance to check for weight variation. Weight variation specification as per U.S.P is shown ahead.

- **Tablet Thickness**

Micrometer was used for the measurement of thickness of tablet. Ten tablets were taken and their thickness recorded. The mean value was calculated and standard deviation was determined.

- **Hardness**

Hardness or tablet crushing strength (fc) means the force required to break a tablet in a diametric compression was determined using Pfizer/Monsanto tablet hardness tester. It is expressed in kg/cm2. The hardness of Rapimelts is kept lower than conventional tablet because increase in hardness delays the disintegration of tablet. Five tablets from each batch were randomly selected and average hardness was calculated and standard deviation was determined.

Results

Metoclopramide HCl was found to be 183˚ C which was similar to that of standard values thus indicating the purity of the drug and all other laboratory observations were almost similar to the reported values.

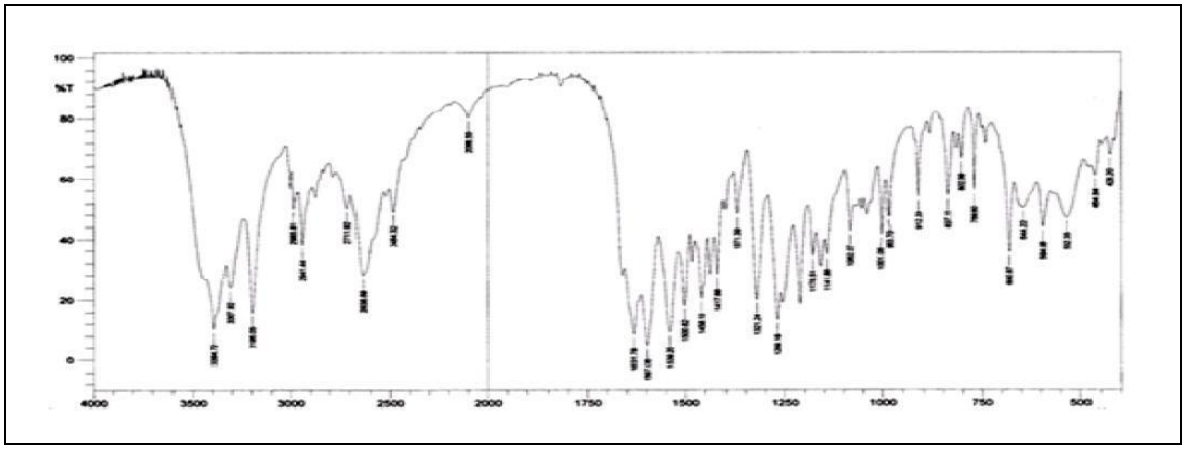

Figure 1: Standard FTIR Spectra of Metoclopramide HCl.

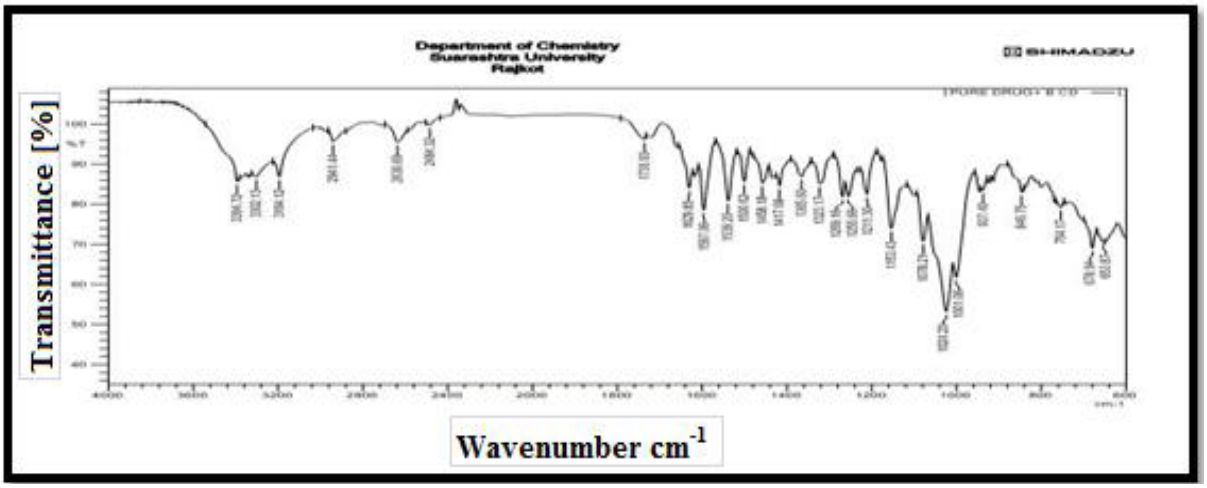

Figure 2: FTIR spectra of Metoclopramide HCl and β Cyclodextrin (1:1ratio)

Discussion

The aim of the present investigation was to Formulate, designed, and evaluates plant agoovata mucilage used as a natural superdisintegrant was to developed and optimized rapimelts containing Metoclopramide HCL. To purpose of the study isolate mucilage from the plantago ovata husk powder by pregelatinization method and prepared priliminary trial batches of repimelts using β cyclodextrin with different ratio of drug and polymer. Evaluate the drug polymer complex and finally which polymer and ratio of drug and polymer is better to formulate final formulation. To achieve taste masking of drug. prepare preliminary trial batches of rapimelts using plantago ovata mucilage as natural superdisintegrant and crosspovidone as synthetic superdisintegrant by direct compression method. Rapimelts tablet of metoclopramide Hcl tablets by determination of range of technological parameters. Dissolution profile suggested that tablet prepared with Plantago ovate mucilage were capable of releasing up to 90 % drug within 15 minutes in phosphate buffer 6.8 pH, by an appropriate combination of excipients it is thus possible to obtain Rapimelts tablet of metoclopramide Hcl tablets using simple and conventional technique.

Conclusion

To purpose of the study isolate mucilage from the plantago ovata husk powder by pregelatinization method and prepared priliminary trial batches of repimelts using β cyclodextrin with different ratio of drug

and polymer. Evaluate the drug polymer complex and finally which polymer and ratio of drug and polymer is better to formulate final formulation. To achieve taste masking of drug. prepare preliminary trial batches of rapimelts using plantago ovata mucilage as natural superdisintegrant and crosspovidone as synthetic superdisintegrant by direct compression method. Rapimelts tablet of metoclopramide Hcl tablets by determination of range of technological parameters. Dissolution profile suggested that tablet prepared with Plantago ovate mucilage were capable of releasing up to 90 % drug within 15 minutes in phosphate buffer 6.8 pH, by an appropriate combination of excipients it is thus possible to obtain Rapimelts tablet of metoclopramide Hcl tablets using simple and conventional technique.

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