Human Journals

Research Article

October 2021 Vol.:22, Issue:3

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Research Article on To Investigate, Develop and Evaluate Anti Hemorrhoid Tablet from Black Mustard Seed and Banana Powder



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Submitted:20 September 2021Accepted:26 September 2021Published:30 October 2021





www.ijppr.humanjournals.com

Keywords: Black Mustard seed powder, Banana powder, antihemorrhagic, sinigrin, vitamin, herbal medicine

ABSTRACT

The present study was aimed to investigate, develop and evaluate Antihemorrhoid tablets from black Mustard seed and Banana powder. Hemorrhoid is found most common gastrointestinal disorder. It is a chronic condition in are swollen and inflamed veins around your anus or in your lower rectum are called piles or hemorrhoids. The two types of hemorrhoids are 1) External hemorrhoids, which form under the skin around the anus 2) Internal hemorrhoids, which form in the lining of the anus and lower rectum. Allopathic treatment for hemorrhoids is too costly so focusing on herbal medicines is necessary. Black Mustard Seed in chemical constituent 35-40% of fixed oil, glycoside known as sinigrin and enzyme myrosin and Banana powder consists of numerous important active chemical constituent carbohydrate, sugar, dietary fiber, vitamins (vitamin C, choline, pyridoxine (B6), pantothenic acid (B5) from mustard seed powder and banana powder show antihemorrhagic activity. Manufacturing of tablets was done by using the wet granulation method on lab level tablet press (CEMACH) by the wet granulation method. Evaluations tests performed on tablets such as Hardness, Weight variation, friability, disintegration test, etc.

INTRODUCTION

Oral delivery of drugs is the most preferable route of drug delivery due to the ease of administration, patient compliance, and flexibility in formulation, etc. Many of the drug delivery systems available in the market are oral drug delivery-type systems. Approximately 50% of the drug delivery systems available in the market are oral drug delivery systems and historically too, oral drug administration has been the predominant route for drug delivery. It does not pose a sterility problem and minimal risk of damage at the site of administration.

Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for the immediate release of drug for rapid absorption.

These immediate release dosage forms have some limitations such as:

- 1) Drugs with a short half-life require frequent administration, which increases chances of missing doses of the drug leading to poor patient compliance.
- 2) A typical peak-valley plasma concentration-time profile is obtained which makes attainment of the steady-state condition difficult.
- 3) The fluctuating drug levels may lead to precipitation of adverse effects especially of a drug with a small therapeutic index, whenever overmedication occurs.

To overcome the drawbacks of conventional drug delivery systems, several technical advancements have led to the development of a controlled drug delivery system that could revolutionize the method of medication and provide several therapeutic benefits.

Design and formulation of oral sustained release drug delivery system:

The oral route of administration is the most preferred route due to flexibility in dosage form, design, and patient compliance. But here one has to take into consideration, the various pH that the dosage form would encounter during its transit, the gastrointestinal motility, the enzyme system, and its influence on the drug and the dosage form. The majority of oral sustained release systems rely on dissolution, diffusion, or a combination of both mechanisms, to generate a slow release of drug to the gastrointestinal tract. Theoretically and desirably a sustained release delivery device should release the drug by a zero-order process which would result in a blood-level time profile similar to that after intravenous constant rate

infusion. Plasma drug concentration profiles for conventional tablet or capsule formulation, a sustained release formulation, and a zero-order sustained release formulation.

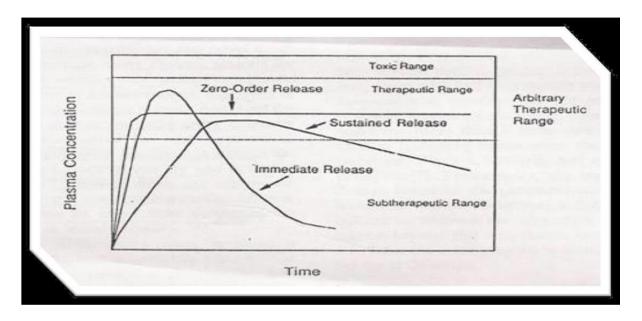


Figure No. 1: Plasma Concentration-profiles Vs Time (sustained-release formulation and zero-order formulation)

Sustained-release constitutes any dosage form that provides medication over an extended time or denotes that the system can provide some actual therapeutic control whether this is temporal, spatial nature, or both. A sustained-release system generally does not attain zero-order type release and usually tries to mimic zero-order release by providing the drug in a slow first order. Repeat action tablets are an alternative method of sustained release in which multiple doses of the drug are an alternative method of sustained release, in which, multiple doses are contained within a dosage form and each dose is released at a periodic interval.

The Delayed-release system, in contrast, may not be sustained, since often the function of these dosage forms is to maintain the drug in the dosage for some time before release, for example. Enteric-coated tablet. A sustained release dosage form will provide a therapeutic concentration of the drug in the blood that is maintained throughout the dosing interval with a reduction in a peak concentration ratio.

Advantages of Sustain-Release Dosage Forms

- 1. Reduction in frequency of intakes.
- 2. Reduce side effects.

- 3. Uniform release of drug over time.
- 4. Better patient compliance and reduced patient care time.

Disadvantages of Sustained Release Drug Delivery

- 1. Increased cost.
- 2. Increased potential for first-pass clearance.
- 3. Need for additional patient education and counseling.
- 4. Toxicity due to dose dumping.
- 5. Unpredictable and often poor *in vitro-in vivo* correlation.
- 6. Risk of side effects or toxicity upon fast release of contained drug (mechanical failure chewing or masticating, alcohol intake).

Factors Affecting the Oral Sustain Release Dosage Form Design

A) Pharmacokinetics and pharmacodynamics factor

1) Biological half-life

Drug with a biological half-life of 2-8 hours is considered a suitable candidate for sustain release dosage form since this can reduce dosing frequency. However, this is limited in that drugs with each dosage unit maintain sustained effects, forcing the dosage form itself to become limitingly large.

2) Absorption

The rate of absorption of a sustained formulating depends upon the release rate constant of the drug from the dosage form, and for the drugs that are absorbed by active transport, the absorption is limited to the intestine.

3) Distribution

The distribution of drugs into tissues can be an important factor in the overall drug elimination kinetics. Since it not only lowers the concentration of circulating drug but it also can be rate-limiting in its equilibrium with blood and extravascular tissue, consequently apparent volume of distribution assumes different values depending on the time course of

drug disposition. Thus, for the design of sustain release products, one must have information on the disposition of the drug.

4) Metabolism

The metabolic conversion to a drug is to be considered before converting into another form. Since as long as the location, rate, and extent of metabolism are known a successful sustain release product can be developed.

B. Drug properties relevant to sustain release formulation:

1. Dose size

A dose size of 500-1000mg is considered maximal for a conventional dosage form. This also holds for sustain release dosage forms. Since dose size consideration serves to be a parameter for the safety involved in the administration of large amounts with a narrow therapeutic range.

2. Ionization, pKa, and aqueous solubility

Most drugs are weak acids or bases and for a drug to get absorbed, it must dissolve in the aqueous phase surrounding the site of administration and then partition into the absorbing membrane.

3. Partition coefficient

The bioavailability of a drug is largely influenced by the partition coefficient, as the biological membrane is lipophilic in nature transport of the drug across the membrane largely depends upon the partition coefficient of the drug. Drugs having a low partition coefficient are considered as a poor candidate for the sustain release formulation as they will be localized in the aqueous phase e.g. Barbituric acid and vice versa.

4. Drug stability

When drugs are orally administered, they come across acid-base hydrolysis and enzymatic degradation. In this case, if the drug is unstable in the stomach, a drug release system that provides medication over an extended period is preferred, whereas, in contrast, the drug unstable in the intestine will face the problem of less bioavailability.

Various treatments on piles or Hemorrhoids

1. Black Mustard seed

Grind a few mustard seeds and add them to a bowl of yogurt. You can snack on this mixture before your breakfast and it will help both internal and external piles conditions.

2. Goat milk is the best remedy for treating piles

You can powder a few mustard seeds and add them to a glass of goat milk to relieve you from piles; both internal and external.

You can also run a few drops of goat milk to your external pile's conditions and it will soothe down the irritation.

3. How is banana beneficial in treating piles?

Fresh fruits are great for treating any and every form of digestion-related issues. A healthy digestive system helps in the proper absorption of nutrients and ensures a healthy immune system. However, if your digestion is not good, it might lead to several ailments like piles, fissures, and colon cancer.

Well, when it comes to treating piles, ripe bananas happen to be the best natural remedy to treat piles. Read on to know how it is effective in curing hemorrhoids.

Banana works as a natural laxative, the slippery inside of banana has ample carbohydrates. Consuming bananas daily can not only make your digestion better but at the same time, can give you miraculous results in curing piles.

The sugars present in bananas are loaded with antibiotic qualities, which can heal the infected area by kicking out bacterial growth. Moreover, through a process of osmosis, bananas can help in reducing inflammation. In this process, the water is drawn out of the cells and this further reduces the pain due to piles.

Hemorrhoids

Hemorrhoid is found most common gastrointestinal disorder in human beings by general practitioners. Several modern treatment modalities and diagnoses are available for hemorrhoids. Since ancient times herbal medicines are in use as first aid for hemorrhoid treatment, now a day such treatments also become more popular in urban communities.

In normal cases, the hemorrhoidal disease can be treated by dietary modifications and tropical medications, which temporarily reduce symptoms, pain, and swelling. In the case of older hemorrhoids, several options are available for treatment like; non-surgical and surgical methods, but these treatments are costly and have complications after treatments. Botanicals are the best option as an alternative treatment for hemorrhoids.

There are several botanicals available in form of oral cream, ointments, capsules, tablets, powder, and oils for hemorrhoid treatment. The preset compilation is the outcome of nine years of in-depth research on hemorrhoids and their treatment with herbs and botanicals as an alternative to surgical options for the betterment of society.

This topic covers the formulation of anti hemorrhoids tablets from the mustard seeds powder and banana powder for the treatment of hemorrhoids.

Hemorrhoids are swollen, enlarged veins that form inside and outside the anus and rectum. They can be painful, uncomfortable, and cause rectal bleeding. Hemorrhoids are also called piles. We're all born with hemorrhoids, but at baseline, they don't bother us. It's only when they become swollen and enlarged that they produce irritating symptoms.

Background of the research

Hemorrhoids are a common condition defined as vascular structures that extend from the subcutaneous anterior venous vascular plexus in the anal region to the smooth muscle of the anal sphincter through the conjoined longitudinal muscle (Man, *et al.*, 2013).

Hemorrhoids are also explained as enlarged veins in the anus or lower rectum with Symptoms of itching around the anus irritation and pain around the anus, itchy or painful lump or swelling near the anus, Fecal leakage, painful bowel movements, and bleeding from ruptured veins.

There are two main types of hemorrhoid

- 1) External hemorrhoid
- 2) Internal hemorrhoid

Internal hemorrhoids are further graded based on their appearance and degree of

prolapse:

(1) Grade I: Non-prolapsing hemorrhoids

(2) Grade-II: Prolapsing hemorrhoids on straining but reduce spontaneously

(3) Grade III: Prolapsing hemorrhoids requiring manual reduction

(4) Grade IV: Non-reducible prolapsing hemorrhoids which include acutely thrombosed

(Lohsiriwat, 2015).

Several actors are involved for hemorrhoids such as Irregular bowel habits (constipation or

diarrhea), Lack of exercise, Nutritional factor (a low-fiber diet), Increased intra-abdominal

pressure (prolonged straining, an intra-abdominal mass, or pregnancy), genetics, absence of

valves within the related veins, Aging, Obesity, Prolonged sitting, Chronic cough, Pelvic

floor dysfunction (Man, et al., 2013).

The true prevalence of hemorrhoids is unknown; however, recent evidence has suggested an

increased prevalence of hemorrhoids over time. In 1990, an epidemiology study of

hemorrhoids in the United State revealed a prevalence rate of 4.4%, whereas some reports in

the 21 century from South Korea and Austria yielded a prevalence of hemorrhoids in an adult

population of 14.4% and 38.9%, respectively. It has been estimated that 25% of British

people and 75% of American citizens will experience hemorrhoids at some time in their lives,

especially in pregnant women and elderly adults (Lohsiriwat, 2015).

In Asian countries also Hemorrhoids are recognized as one of the most common medical

conditions in the general population with a prevalence of 39% of the population, of whom

44.7% are symptomatic Both genders report peak incidence from age 45 to 65 years (Yeo,

2014).

MATERIALS AND METHODS

Following materials used in research work are of analytical grade or best possible pharma-

grade available were used as supplied by the manufacturer.

1. Materials Used

Table No. 1

| Sr. No. | Material | MFG By |
|------------|-----------------|-------------------------------------|
| 1. | Mustard power | M.V village kerla. |
| 2. | Banana power | M.V village kerla. |
| 3. | Starch | HiMedia Laboratories Ltd, Mumbai. |
| 4. | Methylcellulose | HiMedia Laboratories Ltd, Mumbai. |
| 7. | Talc | NR Chem, Mumbai. |
| 8. | Lactose | Merck Specialties limited., Mumbai. |
| 9. | Amaranth | Merck Specialties limited., Mumbai. |

2. Selected excipients used in formulations

Table No. 2

| Sr. NO | EXCIPIENT USED | FUNCTION |
|-----------|------------------|-----------------|
| 1 | Starch — MA | Disintegrant |
| 2 | Methyl cellulose | Binder |
| 3 | Lactose | Diluent |
| 5 | Talc | Glidant |
| 6 | Amaranth | Colouring agent |

3. Pre-formulation studies

Pre-formulation testing is the first step in the rational development of dosage forms of a drug substance. It can be defined as an investigation of the physical and chemical properties of a drug substance alone and when combined with excipients.

The overall objective of pre-formulation testing is to generate information useful to the formulator in developing stable and bioavailable dosage forms which can be mass-produced.

Quantities of ingredients were taken by accurate weighing on digital balance, mixed all content in mortar and tablets were prepared by wet granulation method.

A. Wet Granulation Method:

1. Starch was weighed and made into an emulsion and cooked well on a water bath until

translucent semisolid mass was formed. The Amaranth solution was prepared by using the

required quantity of water separately.

2. The weighed quantities of excipients were mixed thoroughly with powder drug, the cooked

starch and Amaranth solution were added slowly till the powder became a damp mass.

3. This damp mass was passed through sieve number 22# and dried in an oven at a

temperature of 105°C until granules were dried properly.

4. Then the dried granules are subjected to compression.

5. Finally, the tablets were compressed with 8 mm punches by using a multiple punch Tablet

press machine.

PREFORMULATION STUDY

1. Bulk Density:

It refers to the packing of particles. Bulk density is used to determine the amount of drug that

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occupies the volume in g/ml.

Procedure:

The weighted quantity of powder was transferred into a 100ml measuring cylinder without

tapping during transfer. The volume occupied by the drug was measured.

Bulk density was calculated by using the formula:

Bulk Density =m/Vi

Where,

m = mass of the blend,

Vi = Bulk volume

2. Tapped density:

Weighed accurate quantity of powder sample was into a graduated cylinder. The volume occupied by the drug was noted down. Then cylinder was subjected to 100, 200 & 300 taps in tap density apparatus.

Tapped density was calculated.

Tapped Density = m / Vt

Where,

m = mass of the blend,

Vt = tapped volume

3. Carr's Index (Compressibility):

The compressibility index and Hausner's ratio have measured the property of powder to be compressed. The packing ability of powder material was evaluated from a volume change, which is due to rearrangement of packing occurring during tapping.

It was indicated as Carr's compressibility index was calculated by the following formula:

4. Hausner's ratio:

It is a measurement of frictional resistance of tablet blend. The ideal range should be 1.2-1.5. It was determined by the ratio of tapped density and bulk density.

Hausner 'Ratio = Tapped Density/Bulk Density

5. Angle of Repose (θ):

It is defined as the maximum angle that can be obtained between the free-standing of powder heap and horizontal plane, which is determined by the equation;

The angle of repose $(\theta) = \tan(1/r)$

Where,

 θ = Angle of repose;

h = height of powder heap

r = Radius of the powder cone.

Procedure:

Weighed quantity of the powder sample was passed through a funnel kept at a height of 2cm from the base. The powder was passed till it forms a heap and touches the tip of the funnel. The radius was measured and the angle of repose was calculated by using the above formula.

6. Flow Rate: -

- 1. Weighed the accurate quantity of powder samples.
- 2. Place a cotton plug at the neck of a clean and dry funnel of stem diameter 1-2.5cm.
- 3. Place powder sample in the funnel.
- 4. Remove the plug from the neck and record the total time required for all the powder to flow.

Calculate flow rate by using formula.

Flow Rate = Weight powder/time required to flow

7. Moisture contents:

- 1. Weigh 1.5g of sample in a porcelain dish containing 6-8 cm diameter and 2-4 cm depth in
- it. 2. Dry the sample in an oven at 1050 C. cool & weigh.

Calculate the moisture contents by using the formula:

Moisture Contents (%) =Final weight -Initial weight×100

8. Total Ash Value:

Used to determine the quality and purity of the crude drug and to establish the identity of.

Procedure:

- 1. Weigh 2gm of powder drug into the crucible.
- 2. Ignite the sample on the burner (flame) until all the carbon is burned off.

3. Cool it and weigh the ash.

4. Calculate the percentage of total ash with references to the air-dried sample of the crude drug.

4. Evaluation of prepared tablets:

1. General appearance:

Physical examination is done by visual inspection, Colour, Odour, Size, Shape Unique Identification Marking, etc.

2. Thickness:

Ten Tablets were selected randomly from individual formulations and thickness was measured by using the vernier caliper scale, which permits accurate measurement. The average of 3 readings was taken as the thickness of the tablet.

3. Weight variation:

Twenty tablets were taken randomly, weigh individually and the average weight was determined. The individual tablet weight was compared with the average tablet weight.

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4. Hardness:

Tablets require a certain amount of strength or hardness, to withstand mechanical shocks of handling in manufacture, packaging, and shipping. The most widely used apparatus to measure tablet hardness (strength) is the Pfizer hardness tester.

Method:

Ten tablets were randomly selected and hardness was measured in Pfizer hardness tester. The average of 3 readings was taken as the hardness of the tablet.

5. Friability:

Friability is related to the ability of the tablet to withstand both shocks and abrasion without crumbling during manufacturing, packing, transportation, and consumer handling. Friability can be evaluated using a friability test apparatus friabilator. Compressed tablets that lose less than 0.5% to 1.0% in weight are generally considered as acceptable.

Method:

Ten tablets were randomly select and weighed (initial wt.) and then transfer into a friabilator. It was subjected to 100 revolutions in 4 minutes. The tablets were dedusted and reweighed (final wt). These two weights (i.e., initial and final) were applied to calculate the friability.

% Friability = (Initial Weight – final weight) /initial weight $\times 100$

6. Drug content uniformity

10 tablets were weighed from each batch and the average weight is calculated. All tablets were crushed and powder equivalent to 80 mg drug was dissolved in phosphate buffer 6.8 and the volume was made up to 100 ml with pH 6.8 phosphate buffer. From the stock solution, 1ml solution was taken in a 10 ml volumetric flask and the volume was made with pH 6.8 phosphate buffers.

The solution was filtered and absorbance was measured spectrophotometrically at 249 nm against pH 6.8 phosphate buffer as a blank. The number of drugs present in one tablet was calculated.

7. Disintegration test

In-vitro disintegration time was measured using the USP disintegration test apparatus. For the DT test randomly one tablet was selected from each batch and the test was performed in 900 ml distilled water at 37 ± 0.5 °C temperature and the rate of 30 ± 2 cycles/min.

8. Stability studies

The stability of a drug has been defined as the ability of a particular formulation in a specific condition, to remain within its physical, chemical, therapeutical, and toxicological specifications. There one of stability testing is to provide evidence on how the quality of drug formulation varies with time under the influence of various environmental conditions such as temperature, humidity, light. From this study we know about recommended storage conditions, re-test periods and shelf-life of the drug can be established.

5. Stability studies are important for the following reasons.

1. This is an assurance given by the manufacturer that the patient would receive a uniform dose throughout the shelf life.

- 2. The drug control administration insists on manufacturers conducting the stability studies, identity, strength, purity, and quality of the drug for an extended period in the conditions of normal storage.
- 3. Stability testing prevents the possibility of marketing an unstable product. Both physical and chemical degradation of drugs can result in an unstable products.

OBSERVATIONS AND RESULTS

1. FTIR Studies

Potential chemical interactions between the drug and polymer may change the therapeutic efficacy of the drug. To investigate the possibilities of chemical interaction between drugs and excipients. FTIR spectra of pure drug and optimized formulations were analyzed over the range 400-4000cm-1. Compatibility studies were performed using FT-IR Spectrophotometer.

The FT-IR spectrum of pure mustard powder and banana powder drug was compared with the FT-IR spectrum of the physical mixture of mustard powder and banana powder (starch, methylcellulose, lactose, Talc). The spectra for all formulations are shown below figure.

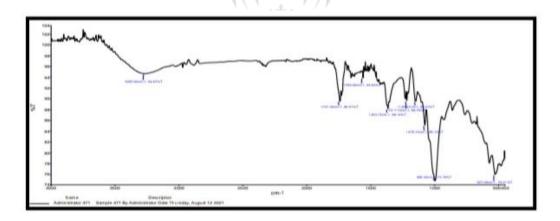


Figure No. 2: FTIR spectra of banana powder

FTIR MUSTARD SEED POWDER

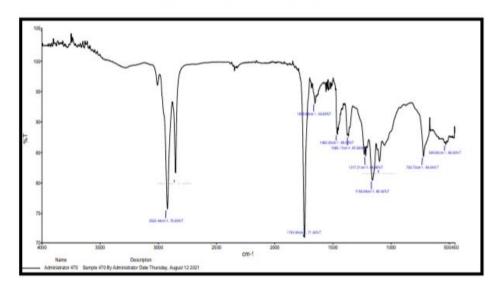


Figure No. 3: FTIR Spectra of Black Mustard Seed

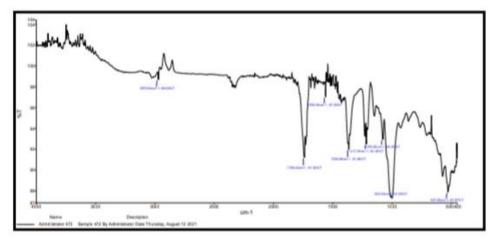


Figure No. 4: FTIR Spectra Starch

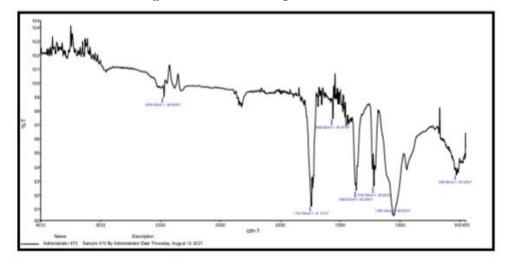


Figure No. 5: FTIR Spectra Methyl cellulose

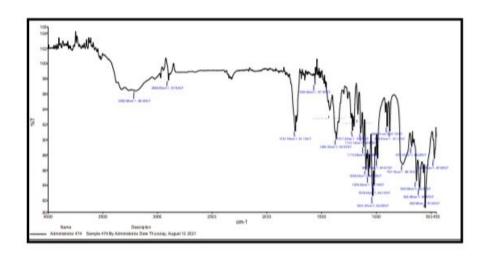


Figure No. 6: FTIR Spectra Lactose

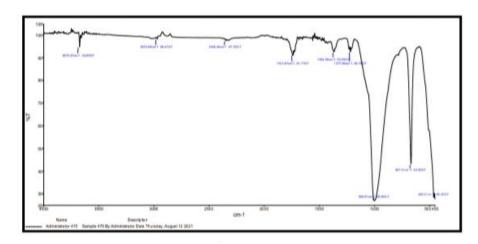


Figure No. 7: FTIR Spectra Talc

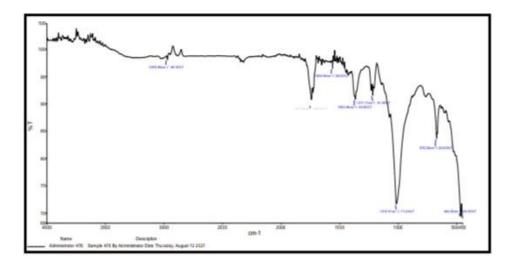


Figure No. 8: FTIR drug and excipients

Table No. 3: FTIR Peak Drug + Excipient

| Functional groups | Standard frequency | Observed peak |
|-------------------|--------------------|---------------|
| C-H Stretching | 2850-3000 | 2970.89 |
| C=O Stretching | 1670-1820 | 1741.90 |
| N-O Stretching | 1515-1560 | 1559.99 |
| -C-H Bending | 1350-1480 | 1364.96 |
| C-N Stretching | 1080-1360 | 1217.11 |
| C-F Stretching | 1000-1400 | 1013.91 |
| C-Cl Stretching | 600-800 | 670.29 |
| C-I Stretching | 500 | 464.20 |

The FTIR spectrum analysis showed that there is no appearance or disappearance of any characteristic peaks of pure mustard powder and banana powder and in the physical mixture of drug and excipients. The presence of peaks at the expected range confirms that the materials taken for the study are genuine. The results were shown in the table Due to stretching C-H, N-O, C=O, C-N, C-Cl, C-F, C-I respectively in optimized formulations also these peaks were well preserved with additional peaks which correspond to the excipients used in the formulation.

1. Preformulation study of mustard seed powder and banana powder

Table No. 4: Preformulation study of powder Drug

| Sr. No | Parameter | Specifications |
|--------|-----------------------|----------------|
| 1 | Bulk density (g/ml) | 0.65 |
| 2 | Tapped density (g/ml) | 0.572 |
| 3 | Carr's index (%) | 16.30 |
| 4 | Hauser's ratio | 1.27 |
| 4 | Porosity (%) | 19.25 |
| 5 | Angle of repose | 320 78" |
| 6 | Moisture content (%) | 11 |
| 7 | Flow rate (gm/sec) | 0.66 |
| 8 | Ash value | 0.31 |

2. Preformulation study of Granules

In this table Preformulation studies of granules, F3 and F5 batches or formulation show acceptable bulk density, tapped density, angle of repose, porosity, Carr's index.

Table No .5: Preformulation studies of granules

| Parameter | F1 | F2 | F3 | F4 | F5 | F6 | F7 |
|-------------------------|---------|--------|--------|--------|--------|-------|--------|
| Bulk density | 0.57 | 0.64 | 0.75 | 0.77 | 0.52 | 0.69 | 0.84 |
| Tapped density | 0.92 | 0.842 | 0.772 | 0.623 | 0.642 | 0.542 | 0.172 |
| Carrs index | 37.33 | 21.25 | 17.22 | 25.36 | 30.20 | 19.23 | 34.26 |
| Hausner ratio | 1.495 | 1.751 | 1.652 | 1.772 | 1.627 | 1.324 | 1.246 |
| Porosity | 22.25 | 16.33 | 11.23 | 24.22 | 32.57 | 28.56 | 35.23 |
| Angle of repose | 34061'' | 31025" | 30025" | 32011" | 31027" | 31088 | 32025" |
| Moisture content | 9 | 7 | 6 | 5 | 7 | 6 | 6 |
| Flow rate | 0.54 | 0.84 | 0.72 | 0.63 | 0.65 | 0.59 | 0.73 |

3. Evaluation of Formulation

a. Physical evaluation of tablet

After tablet punching various quality-control tests were carried out, which demonstrated the following organoleptic properties color, odor, and shape.

All formulations (**F1 to F7**) were found to be Gray, odorless, and round shape.

Table No. 6: Evaluation of Tablet

| Parameter | | | | Formulation Batches | | | |
|--------------------|-------|-------|-------|---------------------|----------------|-----------|-------|
| General appearance | | | | Formulation Batches | | | |
| F1 F2 F3 | | | F4 | F5 | F6 | F7 | |
| Colour | Gray | Gray | Gray | Gray | Gray | Gray | Gray |
| Odour | None | None | None | None | None | None | None |
| Taste | None | None | None | None | None | None | None |
| Size (diameter) | 1.7mm | 1.8mm | 1.7mm | 1.7mm | 1.7mm | 1.7mm | 1.7mm |
| Shape | Round | Round | Round | Round | Round | Round | Round |
| Disintegration | 25 | 20 | 23 | 17 | 24 | 16 | 27 |
| time | 23 | 20 | 23 | 17 | 2 4 | 10 | 21 |
| Moisture | 9 | 6 | 8 | 7 | 9 | 6 | 7 |
| content | J | U | O | , | J | U | , |

Table No. 7: Evaluation test of tablet

| Formulation | Thickness (mm)± SD | Weight variation (mg) | Hardness (kg/cm2) | Friability (%) | Drug content (%) |
|-------------|-----------------------|-----------------------------|----------------------|-------------------|------------------|
| F1 | 3.0±0.09 | 250.89±0.12 | 3.3±0.04 | 0.74±0.007 | 98.25±0.044 |
| F2 | 3.5±0.02 | 251.84±0.60 | 3.1±0.03 | 0.82±0.005 | 100.31±0.037 |
| F3 | 3.9±0.01 | 253.14±0.52 | 3.0±0.07 | 0.60±0.031 | 98.54±0.07 |
| F4 | 3.2±0.07 | 248.85±0.13 | 3.2±0.04 | 0.65±0.016 | 99.67±0.087 |
| F5 | 4.0±0.04 | 250.80±0.32 | 3.7±0.08 | 0.725±0.09 | 99.37±0.058 |
| F6 | 3.1±0.09 | 249.90±0.44 | 3.4±0.03 | 0.624±0.01 | 98.97±0.073 |
| F7 | 3.9±0.01 | 252.70±0.60 | 4.0±0.05 | 0.427±0.00 | 101.61±0.08 |

b. Stability studies:

Formulation F3 and F5 were selected for stability study because it gives faster drug release (91.42%) from the tablet and has less disintegration time (29sec) as compared to other formulations. The formulations were evaluated for disintegration time, hardness, friability, and In-Vitro drug release.

Method: The selected formulation was exposed to different storage conditions. As per ICH guidelines for 1 month and evaluated.

Table No. 8: Stability studies

| Parameter | Initial | After 1 month |
|---------------------|---------|---------------|
| Shape | Round | No Change |
| Colour | grey | No Change |
| Hardness (kg/cm2) | 3 | No Change |
| Friability (%w/w) | 0.82 | No Change |
| Disintegration time | 25 sec | 29 sec |
| Weight variation | 249.17 | No change |
| % Drug Release | 91.42% | 88.27% |

CONCLUSION

The research work done on the basis and the selected for the formulation was proved for the use of antihemorrhagic purpose. The Mustard seed powder and Banana powder were used to formulate tablets and evaluate physical parameters and standardize as per pharmacopeial standards. In this formulation, pre-formulation study and physical parameter revealed that all the values were within acceptable limits shown in the table. The herbal formulation shows significant Ant hemorrhoids activity. From the above evaluation parameter, it can be concluded that overall batches the F3 and F5 batches show all parameters in acceptable limits.

Black mustard seed (Brassica nigra) contains antihemorrhagic, antioxidant, and antiinflammatory properties that help in relieving the gum, bone, and teeth, and also used as consuming a spoonful of mustard seed with help of water then cure Stomach disorders like constipation, piles, and fissures. Banana work as a natural laxative, the slippery inside of banana powder has ample carbohydrates. Consuming bananas daily can not only make your digestion better but at the same time, can give you miraculous results in curing piles. The objective of the present study was to investigate the possibility of sustained-release tablets prepared by using different concentrations of cross-linking agents and excipients. The following conclusions can be drawn from the result obtained. The pre-formulation study of mustard seed and banana powder-like the angle of repose, bulk density, tapped density Hausner's ratio, and Carr's index of all formulations were found to be within the standard limits. FTIR studies revealed that there was no chemical interaction between drugs and other excipients. The powder mixtures were compressed into the tablet and evaluated for postcompression parameters like weight variation, thickness, hardness, friability, and drug content. All the formulation batches showed acceptable results. Stability studies showed that the tablets formulations were stable throughout the stability period.

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