INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

Sustain Release Herbal Tablet Containing Ocimum Sanctum and Glycyrrhiza Glabra for The Treatment of Cough

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ARTICLE INFO

Published: 10 Dec. 2024
Keywords:
Herbal Tablet, Treatment of Cough
DOI:
10.5281/zenodo.14353074

ABSTRACT

Coughing is the protective mechanism of the body. In the critical condition like cold it leads to form phlegm in the respiratory system. So, it needs to be cured as early as possible. Some pharmaceutical formulations used to treat coughing were syrups and solutions. These preparations had several disadvantages like bioavailability, dosing frequency and stability problems. To overcome these problems matrix tablet was developed. Matrix tablet consists of polymers which retards the release of the API and gave a prolonged action. Due to the controlled release of the drug, dosing frequency reduced thrice as compared to the liquid dosage forms like syrups. The API used in the formulation was herbal in nature so it had the advantage of having fewer side effects. Reduction in dosing frequency had also helped in increasing the patient compliance. The extracts were loaded in the formulation by mixing it with excipients like polymers, diluents, fillers, lubricants, etc. Direct compression technique was used to formulate the matrix tablets. Pre and post compressional parameters were determined with respect to the standards. The formulations passed all the physical and pharmaceutical parameters. The results of precompressional parameters were good to passable. The results of the post-compressional parameters were satisfactory. The in-vitro release of the formulation was from 18 to 20hrs. Dissolution profile of the drug showed zero order release.

INTRODUCTION

Sustain release means they release small amounts of medication into a patient over an extended time period. Oral route has been the most convenient and popular route of administration for the delivery of drugs. It provides ease of administration, patient compliance and greater flexibility in dosage form design. Sustained delivery of the drugs overcomes the demerits of conventional dosage forms such as short half life and chances of missing the dose. Sustained release dosage forms have the advantage of achieving uniform drug plasma level and less side- effects. Cough is the most common disorder that is faced by everyone. Cough is the natural protective mechanism of the body that removes foreign

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

particles, toxins, secretions or mucous from the bronchi and bronchioles. Cough manifests in common cold, so it can lead to serious illness like asthma, pneumonia and tuberculosis.

Therefore it needs to be cured as soon as possible. Glycyrrhiza glabra Linn. is a commonly used herb since the period of Ayurveda. Common name is Liquorice and belongs to family Laguminosae. The chief chemical constituent is Glycyrrhizic acid which is responsible for expectorant, tussive, immuno-modulatory and anti inflammatory activity. Glycyrrhizic acid acts at the cough centre in the CNS and suppress the response of cough centre. Therefore decreases mucosal secretion. Ocimum sanctum Linn, belongs to family Labiatae is commonly known as tulsi. The chemical constituent of Ocimum sanctum is Eugenol. It comprises of 23.7%. Hence shows anti-tussive effects.

CLASSIFICATION

- **ON THE BASIS OF RETARDANT MATERIAL USED**
- **Hydrophobic Matrices (Plastic matrices)**

The concept of using hydrophobic or inert materials as matrix materials was first introduced in 1959. In this method of obtaining sustained release from an oral dosage form, drug is mixed with an inert or hydrophobic polymer and then compressed in to a tablet. Sustained release is produced due to the fact that the dissolving drug has diffused through a network of channels that exist between compacted polymer particles. Examples of materials that have been used as inert or hydrophobic matrices include polyethylene, polyvinyl chloride, ethyl cellulose and acrylate polymers and their copolymers. The rate-controlling step in these formulations is liquid penetration into the matrix. The possible mechanism of release of drug in such type of tablets is diffusion. Such types of matrix tablets become inert in the presence of water and gastrointestinal fluid.

- **Lipid Matrices**

These matrices prepared by the lipid waxes and related materials. Drug release from such matrices occurs through both pore diffusion and erosion. Release characteristics are therefore more sensitive to digestive fluid composition than to totally insoluble polymer matrix. Carnauba wax in combination with stearyl alcohol or stearic acid has been utilized for retardant base for many sustained release formulation.

- **Hydrophilic Matrices**

Hydrophilic polymer matrix systems are widely used in oral controlled drug delivery because of their flexibility to obtain a desirable drug release profile, cost effectiveness, and broad regulatory acceptance. The formulation of the drugs in gelatinous capsules or more frequently, in tablets, using hydrophilic polymers with high gelling capacities as base excipients is of particular interest in the field of controlled release. Infect a matrix is defined as well mixed composite of one or more drugs with a gelling agent (hydrophilic polymer). These systems are called swellable controlled release systems. The polymers used in the preparation of hydrophilic matrices are divided in to three broad groups.

- **Cellulose derivatives**

Methylcellulose400 and 4000cPs, Hydroxyethyl cellulose, Hydroxy propyl methyl cellulose (HPMC) 25,100, 4000 and 15000cPs; and Sodium carboxymethylcellulose.

- **Non cellulose natural or semi synthetic polymers**

Agar-Agar; Carob gum; Alginates; Molasses; Polysaccharides of mannose and galactose, Chitosan and Modified starches. Polymers of acrylic acid Carbopol-934, the most used variety.

- **Biodegradable Matrices**

These consist of the polymers which comprised of monomers linked to one another through functional groups and have unstable linkage in the backbone. They are biologically degraded or

eroded by enzymes generated by surrounding living cells or by non enzymetic process in too ligomers and monomers that can be metabolized or excreted. Examples are natural polymers such as proteins and polysaccharides; modified natural polymers; synthetic polymers such as aliphatic poly (esters) and poly anhydrides.

- **Mineral Matrices**

These consist of polymers which are obtained from various species of sea weeds. Example is Alginic acid which is a hydrophilic carbohydrate obtained from species of brown seaweeds (Phaephyceae) by the use of dilute alkali.

- **ON THE BASIS OF POROSITY OF MATRIX**

Matrix system can also be classified according to their porosity and consequently, Macro porous; Micro porous and Nonporous systems can be identified:

- **Macro porous Systems**

In such systems the diffusion of drug occurs through pores of matrix, which are of size range 0.1 to 1 μm. This pore size is larger than diffusant molecule size.

- **Micro porous System**

Diffusion in this type of system occurs essentially through pores. For micro porous systems, pore size ranges between 50 – 200A°, which is slightly larger than diffusant molecules size.

- **Non-porous System**

Non-porous systems have no pores and the molecules diffuse through the network meshes. In this case, only the polymeric phase exists and no pore phase is present.

ADVANTAGES OF MATRIX TABLETS

- Easy to manufacture.
- Versatile and effective
- It has low cost.
- Can be made to release high molecular weight compounds.
- Suitable for both non degradable and degradable systems.
- No danger of dose dumping in case of rupture.
- Can be fabricated in a wide range of size sand shapes.

DISADVATAGES OF MATRIX TABLETS

- The remaining matrix must be removed after the drug has been released.
- The drug release rates vary with the square root of time.
- Achievement of zero order release is difficult.
- Not all drugs can be blended with a given polymeric matrix.
- Water soluble drugs have a tendency to burst from the system.
- Poor in vitro – in vivo correlation.
- Possibility of dose dumping due to food, physiologic or formulation variables.
- Retrieval of drug is difficult in case of toxicity, poisoning or hypersensitivity reactions.
- Reduced potential for dosage adjustment of drugs normally administered in varying strengths.
- Stability problems.
- Increased cost.
- More rapid development of tolerance and counselling.
- Need for additional patient education and counselling.

AIM AND OBJECTIVES

AIM

Formulation and evaluation of sustained release herbal tablet containing ocimum sanctum and glycyrrhiza glabra for the treatment of cough.

OBJECTIVES

- The objective of present study involve preparation of sustain release herbal tablet by using ocimum sanctum and glycyrrhiza glabra and its evaluation.
- To prepare sustain release herbal tablet for treatment of cough.

PLAN OF WORK

Selection of topic
Literature survey
Selection of ingredients
Collection of ingredients
Formulation of Sustained release tablet
Evaluation of Sustained release tablet

LITERATURE SURVEY

TABLE 2

Sr. No.	Paper Title And Its Authors	Detail Of Publication	Findings
1	Deepu. S, Molly. M and Shamna. M.S. (2014). Formulation and Evaluation of Swelling restricted Matrix Tablet containing Metformin Hcl.	IOSR journal of Pharmacy	IOSR journal of Pharmacy
2	Deore S.L, Jaju P.S and Baviskar B.A. (2014). Simultaneous Estimation of Four Anti-tussive Components from Herbal Cough Syrup by HPTLC.	International Scholarly Research Notice	1-7.
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13	Raju. S.K. (2014). Analysis of Anti Cough Preparation Available in Indian Markets.	IOSR-Journal of Dental and Medical Sciences	Vol. 13, 3, 16-18
14	Rathore. A.S, Jat R.C, Sharma. N and Tiwari. R. (2013). An overview: Matrix tablet as Controlled Drug Delivery System.	International Journal of Research and Development in Pharmacy and Life Sciences	Vol.2, 4, 482- 492

MATERIALAND METHODS

TABLE 3: INGREDIENTS

SR.NO.	INGREDIENTS
1	Glycyrrhiza glabra
2	Ocimum sanctum
3	HPMC
4	Poly vinyl pyrrolidone
5	Magnesium stearate
6	Talc
7	Lactose

Glycyrrhiza glabra



Fig 1: Glycyrrhiza Glabra

Common name: Liquorice Scientific name: Glycyrrhiza glabra Domain: Eukaryote

Kingdom Plantae Phylum: Vascular plant Class: Dicotyledons

Family: Fabaceae Genus: Glycyrrhiza

Category: Antioxidant, anti inflammatory and antimicrobial

Uses

- Use to treat respiratory disorder.
- Use to reduce fever.
- Use in treatment of cough.
- Used to reduce stomach ulcer.

Ocimum sanctum



Fig 2: Ocimum Sanctum

Common name: Tulsi

Scientific name: Ocimum tenuiflorum Kingdom: Plantae

Phylum: Vascular plant Class: Magnoliopsida Order: Lamiales Family: Lamiaceae Genus: Ocimum Species: Tenuiflorum

Category: Antioxidant, antimicrobial and anti inflammatory.

Uses

- It is used as antimicrobial.
- It is use to treat bronchial asthma.
- Use to treat diarrhoea.
- It is use to reduce cough.
- To treat various skin diseases.

HPMC



FIG 3: HMPC

Category: Thickening agent / Gelling agent

HPMC is hydrophilic (water soluble), a biodegradable, and biocompatible polymer having a wide range of applications in drug delivery, dyes and paints, cosmetics, coatings, agriculture, and textiles. HPMC is also soluble in polar organic solvents, making it possible to use both aqueous and nonaqueous solvents. It has unique solubility properties with solubility in both hot and cold organic solvents.



Poly vinyl pyrrolidine

Fig 4: Polyvinyl Pyrrolidone

Category: Binder

Polyvinylpyrrolidone (PVP), also commonly called polyvidone or povidone, is a water- soluble polymer compound made from the monomer N-vinylpyrrolidone

Magnesuim stearate



Fig 5: Magnesuim Stearate

Category: Lubricant

Magnesium stearate is a fine white powder that sticks to skin and is greasy to the touch. It's a simple salt made up of two substances, a saturated fat called stearic acid and the mineral magnesium. Magnesium stearate is a white, water-insoluble powder. Its applications exploit its softness, insolubility in many solvents, and low toxicity.



Talc

Fig 6: Talc

Category: Glidant

Talc is a naturally occurring mineral substance. It is added to absorb moisture, smooth or soften products, prevent caking. Talc in powdered form, often combined with corn starch, is used as baby powder. This mineral is used as a thickening agent and lubricant. It is an ingredient in ceramics, paints, and roofing material.

Lactose



Fig 7: Lactose

Category: Diluent

Lactose is a sugar that is naturally found in milk and milk products, like cheese or ice cream. Lactose, is a disaccharide sugar composed of galactose and glucose subunits and has the molecular formula $C_{12}H_{22}O_{11}$. The name comes from lact, the Latin word for milk, and ose means sugar

PREPARATION OF CONTROLLED RELEASE TABLET OF O. SANCTUM AND G. GLABRA

Various batches of Sustained release tablet of Ocimum sanctum and Glycyrrhiza glabra were prepared by direct compression technique with each batch containing 10 tablets with 400 mg of drug. All the ingredients were thoroughly mixed. Then the powder was passed through sieve mesh 20 to get uniform size of particles. Then it was lubricated by adding magnesium stearate and talc. The above powder was compressed with the help of tablet punching machine, After compression the tablets were evaluated for weight variation, hardness, thickness, friability, dissolution, and assay test were determined. The composition of each formulation is given in following table.

Table 4: Formulation Table

Formulation code	G. glabra extract (mg)	O. sanctum extract (mg)	HPMC (mg)	Poly vinyl pyrrolidone (mg)	Magnesium stearate (mg)	Talc (mg)	Lactose (mg)	Total quantity
F1	100	100	50	5	10	15	120	400
F2	100	100	55	5	10	10	120	400
F3	100	100	60	5	10	10	115	400
F4	100	100	40	5	10	10	135	400
F5	100	100	45	5	10	10	130	400

DIGRAM OF TABLET



Fig 8: Sustain release tablet of Ocimum sanctum and Glycyrrhiza glabra

PROCEDURE

Weigh and mix active pharmaceutical ingredients APIs with powdered excipients Prepare the binder solution

Mix binder solution with powders to create a damp mass All ingredients were mixed thoroughly Then the powder was passed through sieve mesh 20 to get uniform size Then it was lubricated by adding magnesium stearate and talc The powder was compressed with the help of tablet punching machine After compression the tablets were evaluated for weight variation, hardness, thickness, friability, dissolution, and disintegration.

PRE-COMPRESSIONAL PARAMETERS

Angle of repose

Maximum angle between the horizontal plane and the surface of pile of the powder is known as angle of repose. 10g of the powder was weighed and

allowed to flow freely through the funnel. The diameter and height of the formulated cone was measured using the scale.

Angle of repose was calculated by using the formula:

Tan Θ= h/r Where,

h = height of power cone R = radius of power cone

Range of pharmaceutical powders:

Table 5: Range of pharmaceutical powders:

Less than 20	Excellent
20-30	Good
30-40	Passable
Above 40	Very poor

Bulk density

A known quantity of powder was poured into the measuring cylinder. Powder was levelled without compacting and read the unsettled apparent volume, V0, to the nearest graduated unit. Bulk density, in gm per ml was calculated by the formula:

Bulk Density = m / Vo Where,

m - weight of the powder, V0 - apparent volume

Tapped density

Tapped density = weight of the powder/tapped volume of the powder

Hausner's ratio

Hausner's ratio is the ratio of the tapped density of granules to the bulk density of granules. Calculated by using the following formula;

Hausner's ratio = Tapped density / Bulk density

Compressibility index

The compressibility index of the granules was determined by Carr's compressibility index Carr's index (%) =True Density−Bulk Density × 100
Bulk Density

POST COMPRESSIONAL PARAMETERS

General appearance: The tablets were subjected to the following evaluation tests.

Weight Variation: The weight variation test was run by weighing 7 tablets individually and compared individual weight to average weight. The tablets meet the USP test, if no more than two tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Hardness test: Tablet require certain amount of resistance or hardness to withstand with the mechanical shocks. Hardness was measured using Pfizer harness tester. Unit of hardness is Kg/cm2 . 10 tablets were chosen randomly from each batch. Hardness of each tablet was noted. Average hardness was determined.

Thickness test: The diameter and thickness of the tablets were measured using Vernier callipers.

Friability: Friability test was performed using Roche friabilator. Ten tablets were weighed and placed in the friabilator, which was then operated for 25 revolutions per minute. After 100 revolutions the tablets was dusted and reweighed.

The percentage friability was determined using the formula Percentage friability =Initial weight−final weight × 100
Initial weight

Drug content: Randomly 5 tablets were taken from each batch. Tablets were powdered separately. Powder equivalent to average weight of tablet each was poured into the 3 different volumetric flasks (100ml). Each volumetric flask was filled with phosphate buffer pH6.8. Powder was dissolved thoroughly in the phosphate buffer pH 6.8. Sufficient quantity of phosphate buffer pH 6.8 was added to make up the volume. Solution was kept for 1hr. Solution was filtered using wattman filter paper. Absorbance of the filtrate was measured at 280nm (Ocimum sanctum) and 282nm (Glycyrrhiza glabra) respectively using double beam U.V. Spectrophotometer. Drug content was determined according to the following formula:

Drug content = Actual dug content
Theorotical drug content
× 100

Swelling index: Study is carried out to evaluate the extent of penetration of media into the tablet. Equilibrium weight gain method was used to determine the swelling index. One tablet from each formulation was randomly chosen. They were immersed in beaker containing media. Initially tablets were immersed in 0.1N HCl for 2hrs. Further it was transferred to the phosphate buffer pH 6.8. At regular intervals tablets were withdrawn, blotted with tissue paper and weighed. This process was repeated for upto 20 hrs.

% weight gain was calculated using equation

$SI = \frac{Wt - w0}{W0} \times 100$

Where,

SI = Swelling Index

W0 = weight of tablet at time zero Wt = weight of tablet at time t

IN-VITRO DISSOLUTION STUDIES:

The in-vitro dissolution studies of formulated tablets of Ocimum sanctum and Glycyrrhiza glabra was performed. 900ml of media was maintained at 37ºC ± 0.5ºC with stirring rate of 100 rpm. 3tablets from each formulation was tested individually in gastric fluid i.e. 0.1N HCl for first 2hrs and then in phosphate buffer pH 6.8 from 3 to 20hrs. 5ml of the sample was withdrawn at regular intervals for 20hrs. Withdrawn sample was replaced by equal volume of the same media. Withdrawn samples were analysed using double-beam UV- Visible spectrophotometer. at determined wavelength of Ocimum sanctum (280nm) and Glycyrrhiza glabra (282nm)

OBSERVATION:

Following evaluation parameters were performed to ensure superiority of prepared herbal tablets:

Table 6: Pre-Compressional Parameters

Sr. No	Pre-Formulation Parameters	Observations
1	Bulk density	0.267g/cm3
2	Tapped density	0.325g/cm3
3	Carr' index	17.84%
4	Hausner' ratio	1.21
5	Angle of repose	27.29

Table 7: Post Compressional Parameters

Sr. no.	Parameters	Observation
1.	Colour	Greenish white
2.	Shape	Flat Faced
3.	Weight variation test	497±5%
4.	Hardness (kg/cm2)	3.3±0.17
5.	Thickness (mm)	4.00±0.005
6.	Friability test (%)	0.81%
7.	Disintegration test (min)	28

RESULT AND DISCUSSION

The formulation was prepared by wet granulation method were tested for pre-formulation studies for the effective evaluation of tablets. All the evaluated pre-formulation parameters i.e. Bulk density, Tapped density, Carr's index, Hausner's ratio, Angle of repose are shown in table

2. Based on the pre-formulation study the flow property of granules was good. Organoleptic evaluation showed that the tablets are greenish white in colour and flat faced shape. The weight variation test, hardness, thickness, friability and disintegration time of tablets were shown in table 3. The results proved that the formulated tablets are stable in all aspects and useful to achieve therapeutic effect on body.

TABLE NO 8: Evaluation of Post compressional parameters of different formulations

Formulation	Hardness	Thickness	Friability	Avg. wt	Swelling index	Drug content
F1	14.10±0.50	8.35	0.464	1000	92.15	92
F2	14.20±0.50	8.30	0.536	980	97.36	93
F3	14±0.50	8.40	0.345	990	98.05	95
F4	14.30±0.20	8.20	0.618	1005	96.80	92
F5	14.10±0.50	8.35	0.321	1000	93.62	91

CONCLUSION

In the present study, sustain release tablets of Ocimum sanctum and Glycyrrhiza glabra were formulated. Sustained release tablet was formulated with HPMC in order to sustain the drug release. The Pre-compressional parameters of sustain release tablet i.e. Angle of repose, Bulk density, Tapped density were studied and found to be in satisfactory. The physical mixtures of the formulations were suitable to formulate the sustain release tablets. Post compressional parameters of sustain release tablet i.e. Weight variation, Hardness, Thickness, Friability, Dissolution and Disintegration were evaluated and the results obtained were satisfactory. Hence the formulations may be suitable for once a day administration

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HOW TO CITE: Darade Prashant*, Dube S. B., Kawade R. M., Sustain Release Herbal Tablet Containing Ocimum Sanctum and Glycyrrhiza Glabra for The Treatment of Cough, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 12, 1106-1116. https://doi.org/10.5281/zenodo.14353074