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ORIGINAL ARTICLE **OPEN ACCESS**

Formulation and Evaluation of Polyherbal Tablets for Treatment of Upper Respiratory Tract Infection

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ABSTRACT

The present study is aimed at the formulation and evaluation of the polyherbal tablet for the treatment of upper respiratory tract infection. Following all the data and knowledge of polyherbal formulation of tablet for treatment of upper respiratory tract infection was prepared using ginger (Zingiber officinale), fennel (Foeniculum vulgare) & black pepper (Piper nigrum). Formulation of polyherbal tablet using these main therapeutically active medicinal drugs is important to meet better patient compliance. The present paper deals with formulation and evaluation of polyherbal tablet using dry extract of selected plants .The present communication also deals with evaluation using FTIR spectral studies showed that there is no interaction between excipients. In conclusion, formulation of polyherbal tablet is protected from upper respiratory infection. Our data confirmed that the selected formulation of polyherbal tablets has acceptable physicochemical features and may be considered as herbal medication for treatment of upper respiratory infection.

Key words: Polyherbal tablet, dry extract, respiratory tract infection.

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INTRODUCTION

Herbal medicines have existed world-wide .and they were used in ancient Chinese, Greek, Egyptian and Indian medicine for various therapies purposes. In Ayurveda, single or multiple herbs (polyherbal) are used for the treatment. The Ayurvedic literature Sarangdhar Samhita' highlighted the concept of polyherbalism to achieve greater therapeutic efficacy. The active phytochemical constituents of individual plants are insufficient to achieve the desirable therapeutic effects. When combining the multiple herbs in a particular ratio, it will give a better therapeutic effect and reduce the toxicity [1]. Ginger (*Zingiber officinale*) may have anti-inflammatory, antibacterial, antiviral, and other healthful properties. Some research indicates that enzymes in ginger can help the body break up and expel this gas, providing relief from any discomfort [2]. Fennel (*Foeniculum vulgare*) containing phytonutrients help clear sinuses. They make a great to aid with bronchitis, congestion and cough as they have expectorant properties [3]. Black pepper (*Piper nigrum*) is particularly used to eradicate parasitic worms and as an appetizer. Black pepper is also used in treating coughs, colds, breathing and heart problems, colic, diabetes, anemia etc. The stomach ailments like dyspepsia, flatulence, constipation and diarrhoea are also treated with black pepper. Black pepper has been used in tooth powder for toothache, as well and an infusion of black pepper can work as a remedy for sore throat and hoarseness. It can also be chewed to reduce throat inflammation. [4]

MATERIAL AND METHODS

Materials:

The *Piper nigrum, Foeniculum vulgare* and *Zingiber officinale* were collected from local market of Pune, Maharashtra, India.

Method:

Powdered material was stored in air- tight container for further use, and preformulation study was done. The interaction studies were carried out to ascertain any kind of chemical interaction of drug with the excipients used in the preparation of tablet formulations. Fourier- transform infrared (DRS) spectra were obtained by using an FTIR-Affinity-1 spectrophotometer (DRS-8000) SHIMADZU, Japan.

Design and development of Tablet: [5-6]

The most common type of tablet is intended to swallow and to release the drug in relative short time thereafter by disintegration and dissolution. The goal of this formulation is the fast and complete drug release in vivo.

Preformulation study:

For making the herbal tablets different blends of powder were prepared. Following drugs and excipients are used for preformulation study.

1) *Piper nigrum*
2) *Foeniculum vulgarae*
3) *Zingiber officinale*

The excipients to be selected are listed here under:

- Lactose
- Starch
- Dibasic calcium phosphate
- Microcrystalline Cellulose
- Aerosil
- Magnesium Stearate

For the manufacturing of tablet direct compression process was used on different proportions of lactose and starch in the formula selected according to preformulation studies. And denoted as F1, F2, F3, F4 and F5. The composition of various formulations given in table no 1 all the ingredients were passed through mesh no. 60# and mix with the powder mix possess good flow properties and good packing ability, thus mix compressed directly**.** The Tablet were compressed each of 100mg weight on 10 station mini press-I rotary tablet compression machine fitted with 8mm flat shape punches.[7-8]Formulation table showing composition of each tablet using different concentration of starch and lactose.

Table no: 1 : Composition of each tablet using different concentration of starch and lactose

Formulation code ---------- Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**
Zingiber officinale	3.04	3.04	3.04	3.04	3.04
Piper nigrum	0.6	0.6	0.6	0.6	0.6
Foeniculum vulgare	4	4	4	4	4
Dibasic calcium phosphate	13	13	13	13	13
Lactose	57	52	47	42	37
Starch	5	10	15	20	25
Magnesium stearate	4	4	4	4	4
Aerosol	5	5	5	5	5
Methyl paraben	0.32	0.32	0.32	0.32	0.32
Propyl paraben	0.04	0.04	0.04	0.04	0.04
Microcrystalline cellulose	8	8	8	8	8
Total	100	100	100	100	100

Pre compression parameters: [9-10]

For above formulations angle of repose, bulk density, tap density, car's index, Hausner's ratio were performed by following procedure-

Flow properties

The tablet blends were evaluated for their bulk density, tapped density, car's index and flow properties. The tapping method was used to determine the tapped density, bulk density and percent Carr's index.

a) Bulk density

A sample of about 50 cm3 of powder that has previously been passed through a US Standard no. 20 sieve was carefully introduced into a 100 mL graduated cylinder. The cylinder was dropped at 2-s intervals on a hard wooden surface 3 times from a height of 1 in. The bulk density was then obtained by dividing the weight of the sample in g by the final volume in cm3 of the sample contained in the cylinder.

b) Tap density

A sample of about 50 cm3 of powder that has previously been passed through a U S standard no. 20 sieve was carefully introduced into a 100 ml graduated cylinder. The cylinder was dropped at 2-s intervals for hundred times from a height of 1 inch until there was no further decrease in the volume of powder. The tap density was then obtained by dividing the weight of the sample in g by the final volume in cm3 of the sample contained in the cylinder.

c) Angle of repose

A glass funnel was held in place with a clamp on ring support over a glass plate. The glass plate was placed on a micro lab jack. Approximately 100 g of the powder was transferred into the funnel (that has previously been passed through a no. 10 size mesh), keeping the orifice of funnel blocked by the thumb. As the thumb was removed, the lab jack was adjusted so as to lower the plate and maintain about 6.4 mm gap between the bottom of the funnel stem and the top of the powder pile. When the powder was emptied from the funnel, the angle of the heap to the horizontal plane was measured with a protractor. The height of the pile (h) and the radius of the base (r) were measured using aĸϭ ruler. The angle of repose was thus estimated by the following formula. Values for angle of repose 30 usually indicate free flowing material and angle 40 suggested a poor flowing material.

Angle of repose = $\tan^{-1}(h/r)$

d) Hausner's ratio

The Hausner ratio was calculated by the formula given below, where dϐB is the freely settled bulk density of the powder and dϐT is the tapped density of the powder. Values less than 1.25 indicate good flow and a value greater than 1.25 indicates poor flow.

Hausner's ratio= dϐT/dϐB

e) Carr's index

The Carr index is an indication of the compressibility of a powder. It was calculated [Table 2] by the following formula, where VB is the freely settled volume of a given mass of powder, and VT is the tapped volume of the same mass of powder. The value below 15% indicates good flow characteristics and a value above 25% indicates poor flow characteristics.

Carr's Index (%) = [(TBD-LBD) * 100]/TBD.

Evaluation of tablet: [11-12]

Following Parameters were studied

a) Tablet Hardness

The strength of tablet is expressed as tensile strength (Kg/cm2). The tablet crushing load, which is the force required to break a tablet into pieces by compression. It was measured using a tablet hardness tester (Monsanto hardness tester)

b) Weight Variation Test

Randomly selected 20 tablets were weighed individually and together in a single pan balance. The average weight was noted and standard deviation was ĸϮ calculated. IP limit for weight variation in case of tablets weighting up to 120 mg is ± 10%, 120 mg to 300 mg is ± 7.5% and more than 300 mg is ± 5%.

PD= (Wavg) – (W initial) / (W avg) x 100

Where PD= Percentage deviation, Wavg = Average weight of tablet, Winitial = Individual weight of tablet.

c) Friability:

Roche friabilator was used for the purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at a distance of 6 inche with each revolution. Pre-weighed 20 tablets were placed in the friabilator, which was then operated for 100 revolutions. Tablets were dusted and reweighed.

d) Disintegration Time

The disintegration time of tablet was measured in water (37˚C) according to USP; Disintegration test apparatus three trials for each batch were performed.

RESULT AND DISCUSSION

From the literature and from the patent search the most favorable excipients are short listed. All excipient chosen as well as their suitability and fitness of purpose each excipient is controlled by pharmacopoeial specification. The excipient are listed hereunder,

- Lactose
- Starch
- Dibasic calcium phosphate
- Microcryalline cellulose
- Aerosol
- Magnesium stearate

The compatibility study of the drug and excipients were studied by FTIR. The
Graphs are shown in following figures.

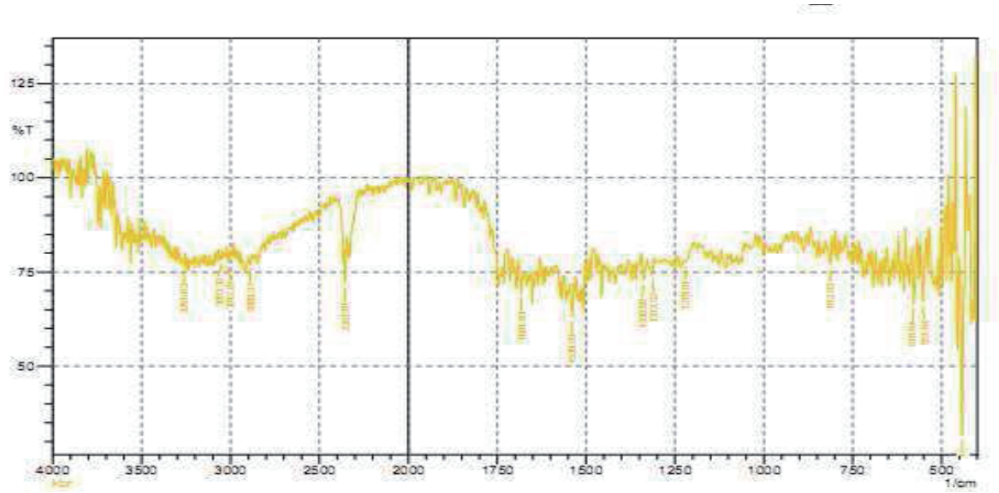

Fig: 1 FTIR spectra of fennel powder

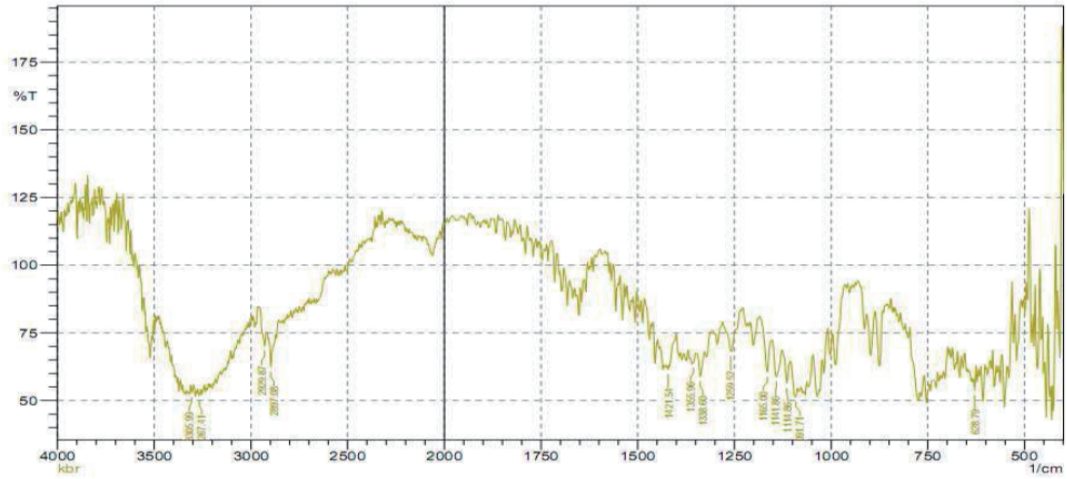

Fig: 2 FTIR spectra of lactose

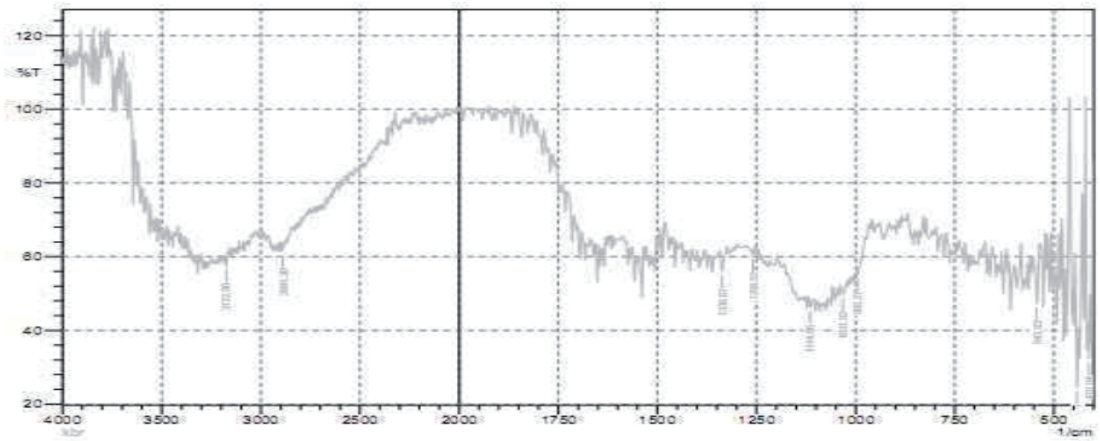

Fig: 3 FTIR spectra of ginger powder

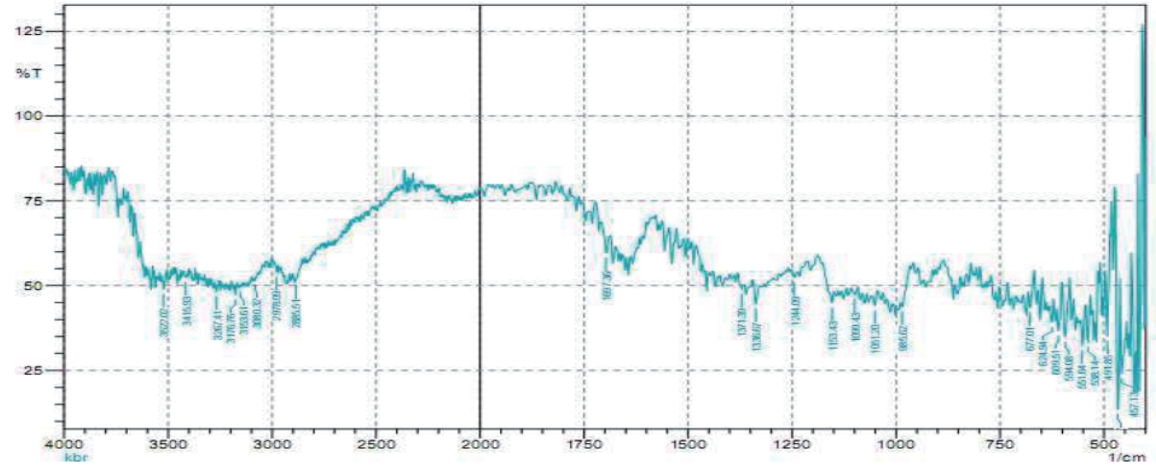

Fig: 4 FTIR spectra of starch

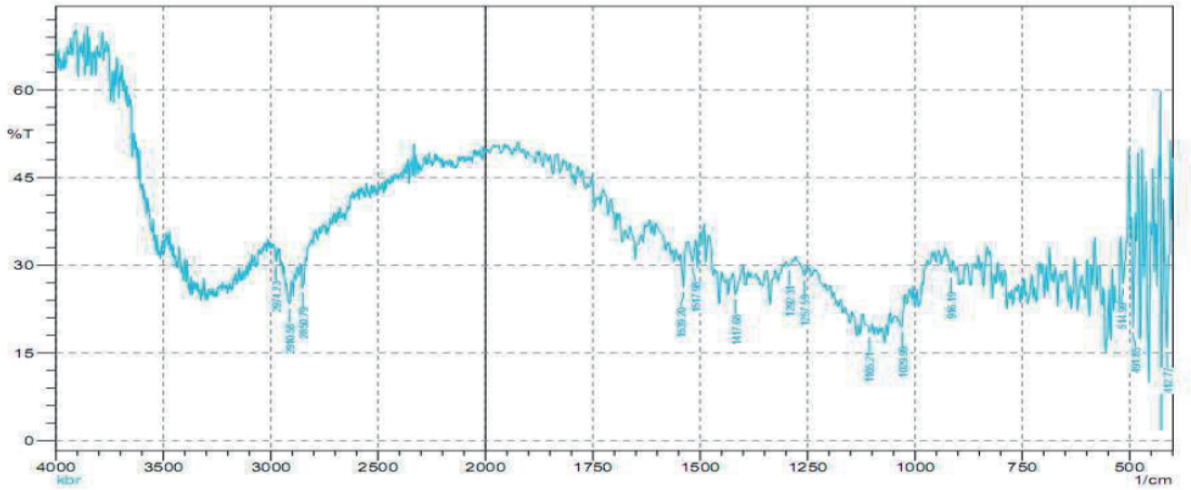

Fig: 5 FTIR spectra of formulated tablet

From above graphs it was observed that there is no interaction between the drugs and excipients. It concludes that there is no incompatibility between drugs and excipients used.

After performing preformulation study we select the one formula which shows the following properties-

Table 2: Preformulation Study of Drug

Sr.no	Formulation	Bulk density	Tapped density	Angle of repose	Car's index	Hausner's ratio
1	F1	0.610	0.810	18.77	24.69	1.32
2	F2	0.590	0.766	19.21	22.97	1.29
3	F3	0.626	0.877	17.74	28.62	1.40
4	F4	0.582	0.782	18.26	25.57	1.34
5	F5	0.619	0.780	15.10	20.64	1.26

From the table 2, it is observed that angle of repose of all formulation are excellent for all formulation. Carr's index was fair to passable and hence there is requirement of addition glidents in above formulation. In the prepared formula (table) amount of aerosil, magnesium stearate and microcrystalline cellulose was kept constant and variation in the lactose and starch was done. By manufacturing tablets from the above formula from the F1- F5. This was evaluated by the using parameters given in table :

Table 3: Evaluation of polyherbal Tablet

Sr.no	Formulation	Colour	Thickness	hardness	Friability	Average weight	Disintegration time	%weight variation
1	F1	White	1.1	5	0.76	116	15	5.1
2	F2	White	1.2	4	0.85	112	10	3.9
3	F3	White	1.2	5	0.63	112	15	7.1
4	F4	White	1.2	4.5	0.66	116	10	3.2
5	F5	White	1.1	4	0.55	112	18	5.4

From the above evaluation parameters of each formula we got the idea about Hardness, friability, average weight, % weight variation in the formula F4 shows the result of above parameters are within the IP limit.

CONCLUSION

The plant material of *Piper nigrum* and *Foeniculum vulgare* were dried and pulverized to make coarse material to make it into fine powder. All the ingredients were passed through mesh no.60.The powder mixture possesses good flow properties and good packing ability, thus mixture compressed directly. Then five different formulations were prepared using different concentrations of additives like bulking agents, glidents, binders, lubricants, adsorbents. These five different formulations of tablets were prepared by direct compression method. Fifty tablets were prepared in each batch. Then evaluation of tablets was performed. Different parameters of evaluation like

Appearance, surface texture, hardness, percentage weight variation, friability, disintegration were performed and results were noted & compared. The evaluation parameters of the formulations were found better in comparison with limits of the information given in reference. It can be concluded that the powders of all extracts and compression method were suitable for the formulation of the tablet. From the evaluation it was concluded that from the various batches of the tablet, the batch four F4 of the formulations was found better.

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