

STUDY OF PIPERINE CONTAINING JELLYS FOR ITS ANTIOXIDANT PROPERTIES, FORMULATION AND EVALUATION PARAMETERS

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Abstract: Piperine is the main compound present in black pepper, and is the carrier of its specific pungent taste, which is responsible for centuries of human dietary utilization and worldwide popularity as a food ingredient. so by using piperine making the jellies because it having a various pharmacological activity like an antioxidant, antiinflammatory ,antihypertensive, anticancer, neuroprotective, anticonvulsant, antidepressants etc., Oral medicated jellies are palatable solid dosage forms administered in the oral cavity, meant to be dissolved in mouth or pharynx for its local or systemic effect. Oral medicated jellies provide several advantages as pharmaceutical formulations however with some disadvantages. Oral medicated jellies as a dosage form can be adopted for drug delivery across buccal route, labial route, gingival route and sublingual route. Multiple drugs can also be incorporated in them for chronic illness treatments.

Keyword: Introduction of piperine and jelly , Preformulation studies of piperine , methods of preparation , evaluation of jelly.

INTRODUCTION OF PIPERINE [1]

Black pepper (*Piper nigrum*), an Indian native spice, has been widely used in human diet for several thousands of years. It is valued for its characteristic sharp and stinging qualities attributed to the alkaloid piperine. While it is used primarily as a food adjunct, black pepper is also used as a food preservative and as an essential component in traditional medicines in India and China. Since the discovery of black pepper's active ingredient, piperine, the use of black pepper has caught the interest of modern medical researchers. Many physiological effects of black pepper, its extracts or its bioactive compound, piperine, have been reported in recent decades. By stimulating the digestive enzymes of the pancreas, piperine enhances digestive capacity and significantly reduces gastrointestinal food transit time.

- Black pepper (*Piper nigrum*) is one of the most widely used among spices valued for its characteristic sharp and stinging qualities.
 - It belongs to the family Piperaceae.
 - cultivated for its fruit (berries) that are usually dried and used as a spice and seasoning.
 - Black pepper is native to southern india and is extensively cultivated in this tropical region.
 - The word “pepper” is derived from the Sanskrit “Pippali”, meaning long pepper.
 - Black pepper (“Maricha” in Sanskrit) is known by other names in the local dialect as “Milagu” (Tamil), “Kuru Mulagu (Malayalam)“Miriyaam” (Telugu), “Miriya Konu” (Konkani), and “Kari Menasu”(Kannada).
 - The fruit, also known as peppercorn, is dark red when fully mature, and a small black wrinkled drupe 5 mm in diameter when dried.

- Black pepper is produced from the green unripe berries of the pepper plant by briefly cooking in hot water.
- The heat ruptures cell walls in the fruit, activating the browning enzymes during drying.
- Cooked berries are dried in the sun for several days, during which the fruit around the seed shrinks and darkens into a thin, wrinkled black layer.

JELLY [2]

Jelly can be define as transparent or translucent non-greasy, semisolid preparation meant for external as well as internal applications” the medicated jelly has through years gained increasing acceptance as a drug delivery system. Several ingredient are now incorporated in medicated jelly. i.e.drug which required fast onset of action, drug which have major absorption site is stomach and small intestine. they may be prepared from natural gums such as tragacanth, pectin, sodium alginate or from synthetic derivatives of natural substance such as methyl cellulose and sodium carboxyl methyl cellulose. Children may consider jelly as more preferred method of drug administration compared with oral liquid or tablet. The use if medicated jelly is feasible as local treatment of disease of the oral cavity as well as treatment of systemic condition.

It is now known so far that medicated preparation for oral administration is used in a jelly dosage form . jellies are semi solid to thick viscous fluid that consists of submicroscopic particles in a somewhat rigid or plastic vehicle.They are transparent or translucent , non-greasy and mucilage type products. The jelly dosage form can be swallowed easily without water.Edible jellied composition include sweet jellies used in food industry ,which are prepared usually used as a base one or two or more of excipient and the like. Their appearance are secured usually for about one year under preservation at room temperature is in cool place. However, none of them can keep preservation stability in terms of pH and the contents of the components at the medical level tests.

Types of Jelly [3,4]

There are three types of jellies.

1. Medicated jelly

These are chiefly used on mucous membrane and skin for their spermicidal, local anesthetics and antiseptic properties. These jellies contain sufficient water. After evaporation of water, jellies provide a local cooling effect and residual film gives protection. For example, ephedrine sulphate jelly is used as a vasoconstrictor to arrest the bleeding of nose.

2. Lubricating jelly

These jellies are used for lubrication of diagnostic equipment such as surgical gloves, cystoscopes, catheters.

3. Miscellaneous jelly

These are meant for various applications like patch testing, electro cardiography.



Fig.1.piperine jelly

PREFORMULATION STUDIES OF PIPERINE [5]

Evaluation of raw material

Prior to development of new dosage form with a drug candidate ,it is essential that certain fundamental physical and chemical properties of the drug candidate and excipient are to be determined.

The procedure for the various taste are given below:

Identification test

1. organoleptic properties

About 1.0 gm of sample was placed in watch glass and what subjectively assessed for appearance , colour, odour and test.

2. Loss on Drying

It was determined As for the LOD testing design to measure the amount of water and volatile matter in the drug when dried in specific condition.

Accurately about 1gm of drug weighed and powder was kept in oven for 1h at 180°C or 6 h at 105°C .

3. pH

pH of taste sample was determined by 2.0% w/v dispersion in carbon free water.

4. Determination of melting range

Glass capillary method was used to determine the melting point . sample filld in a glass capillary tube. The capillary tube was tied with a thermometer and immerse in Thieles tube (containing liquid paraffin as a heating medium) which was heated slowly. The temperature at which drug started melting and temperature at which it melted completely was noted.



Fig.2.melting point of piperine

5. Solubility study

The solubility study of sample was carried out to select the solvent in which the sample is soluble.

Method : in each selective solvent viz; water, methanol ,ethanol, acetone hydrochloric acid, isopropyl alcohol, diethyl ether, phosphate buffer 6.8 ,accurately weighed 10 mg of sample was placed and solubility was visually observed.

6. Flow properties of drug (piperine)

- bulk density
- tapped density
- hausner’s ratio
- Carr’s index
- angle of repose

A. Bulk density

Bulk density or apparent density is defined as the ratio of mass of powder to the bulk volume. Bulk density and tapped density values of blend powder were determined.

Procedure: quantity of powder first first pass through the 40# to break any agglomerates form during the storage. These powder was then introduced into 10 ml of measuring cylinder and the volume occupied by the powder was noted. the bulk density values were calculated using following formula;

$$\text{Bulk density} = \frac{\text{Weight of powder (g)}}{\text{Bulk volume (ml)}}$$

B. Tapped density

Procedure: A quantity of 2.0 grams of powder was first passed through 40#sieve to break in agglomerates formed during the storage. this powder was then introduced into 10 ml of measuring cylinder. The cylinder containing the powder sample manually tapped by rising the cylinder and allow it to drop on their its own weight from constant height. cylinder was tapped for 500 times initially and the tap volume was major to the nearest graduate units the tapping was reported for additionally 750 times and the tap volume was major to the nearest graduated units. If the difference between the 2 volumes is less than 2% then volume is taken rather again tapping for additional 1250 times the tap density values were calculated is been following formula ;

$$\text{Tapped density} = \frac{\text{Weight of powder (g)}}{\text{volume after tapping (ml)}}$$

C. Hausner’s ratio

Hausner’s ratio was calculated by the following formula;

$$\text{Hausner's ratio} = \frac{\text{Tapped density (g/cm}^3\text{)}}{\text{Bulk density(g/cm}^3\text{)}}$$

D. Carr’s index

The compressibility indices of individual blend were calculated using following formula;

$$\text{Carr's index} = \frac{\text{Tapped density - bulk density}}{\text{Tapped density}} \times 100$$

E. Angle of repose

The angle of repose of individual blend was determined by funnel method . the height of funnel was adjusted from surface of graph paper . the accurately weight quantity of powder was allowed to flow through the funnel on a graph paper in such a way that the tip of funnel just touch the heap of powder. the diameter of the powder cone was measured and angle of repose was calculated using the following equation;

$$\text{Tan } \theta = 2h/D$$

Where;

- θ = angle of repose,
- h = height of heap,
- D = diameter of heap

Fig.3.angle of repose of piperine



RESULTS OF PREFORMULATION STUDIES OF PIPERINE

Sr.No.	Test	Reported	Observed
1	Organoleptic proerties	apperance	Crystalline powder
		Taste	Pungent
		Ordur	Odourless
		colour	Yellow
2	Melting Point	Melting range	128-130
3	Identification Test	pH	6.5-7.30
4	Solubility Study	Water	Poor Soluble
		Ethanol	Soluble
		Methanol	Soluble
		Acetone	Slightly Soluble
		HCL	Soluble
		Iso-propyle alcohol	Slightly Soluble
		Diethyl Ether	Slightly Soluble

TABLE NO.1

Sr. No.	Bulk density	Tapped density	Hausner's ratio	Carr's index	Angle of repose
1.	0.46	0.57	1.23	19.29	66.8

TABLE NO.2

Results of flow properties of drug

METHOD OF PREPARATION [6]

Piperine jelly was prepared by heating process

- 1.Firstly gelatin was dissolved in required amount of water by heating, then the required quantity of glycerine, colour and essence was added in this prepared solution with continuous stirring for few time.
- 2.Weigh accurately sufficient quantity of albendazole, gum acacia, sodium alginate, tragacanth, methyl paraben, propyl paraben, sucrose and citric acid were mixed properly and triturate in mortar pestle.
3. The powder was added in prepared solution with continuous stirring for few minutes.
4. Finally the prepared solution of jelly was transferred in moulds and then allow it, for cooling and setting.



Fig.no.4.various formulation of jelly F1 ,F2 ,F3

Ingredient	Quantity %		
	F1	f2	f3
Piperine(mg)	200mg	400mg	500mg
Gum acacia	0.3	0.2	0.3
Sodium alginate	0.2	0.3	0.3
tragacant	0.3	0.2	0.3
gelatin	0.5	0.7	0.6
methyl paraben	0.3	0.2	0.3
propyl paraben	0.3	0.3	0.2
citric acid	0.3	0.3	0.2
sucrose	0.6	0.4	0.5
glycerine	3ml	5ml	4ml
water	q.s.	q.s.	q.s
essence	q.s.	q.s.	q.s
colour	q.s.	q.s.	q.s

TABLE NO.3

EVALUATION OF PIPERINE GELLY

The piperine jelly were evaluated for following parameters,

1. Physical appearance
2. Tickiness ang grittiness
3. pH

4. Viscosity
5. Drag content
6. Stability Study

1. Physical appearance

The albendazole jelly was examined for physical appearance in terms of clarity, texture and Consistency.

2. Stickiness and grittiness

Texture of the albendazole jelly in term of stickiness and grittiness had been evaluated by visual aspersion of the prodefter mildly rubbing the jelly sample between two fingers.

3.Determination of pH

The pH value of 1% aqueous solutions of the prepared jellies were checked by using a calibrated digital pH meter at constant temperature. For the purpose Ig of the weighed formalation was dispersed in 100ml of distilled water and pH was noted. The standard pH of jelly was 2.00-6.05

4. Determination of viscosity

Viscosity of the jelly was carried out by using Brookfield viscometer. As the system is non-Newtonian spindle was used. Viscosity was measured for the fixed time 2 min at 50 rpm. Viscosity of jelly was done by Brookfield viscometer.

5. Drug content (%)

Accurately weighed of jelly formulation was crushed in mortor pestle. A quantity of powder equivalent to 400 mg albendazole was accurately weighed and transferred in 100 ml volumetric flask containing small volume (10 ml) of 0.1 N HCL. The solution was sonicate for 15 min, to disperse the contents and filtered through whatman filter paper. Appropriate dilutions of filtrate were made and the drug content was estimated by using UV-Visible spectrophotometer at 308 nm.

7. Stability studies

Stability studies of the optimized formulations were carried out to know

1. whether the chemical change or degradation of the active ingredient has occurred this may lower the therapeutic potency of active ingredient over storage period.
2. whether any toxic degradation product has formed which may be undesirable.
3. whether gross changes in the physical form of the dosage form have occurred implying poor or substandard quality of ingredients.

In any rational design and evaluation of dosage forms for drugs, the stability of the active components must be major criteria in determining their acceptance or rejection. During the stability studies of the product is exposed to normal conditions of temperature and humidity however the studies will take n

longer time and hence it would be convenient to carry out the accelerated stability studies where the product is stored under extreme conditions of temperature and humidity.

RESULTS OF PIPERINE GELLY

Batches	Clarity	Texture	Consistency	Stickiness	Grittiness	pH	Viscosity	%Drug content
F1	Turbid Form	Smooth	Thick	More Sticky	Non Gritty	6.52	4800	1.040
F2	Turbid Form	Smooth	Thick	Slightly Sticky	Non Gritty	5.39	5333	1.298
F3	Turbid Form	Smooth	Thick	Slightly Sticky	Non Gritty	5.49	6133	1.844

TABLE NO.4

RESULTS OF STABILITY STUDIES

- THE GELLY WAS MELT AT 31 ° C
- THE GELLY WAS STABLE AT -2 ° C

CONCLUSION

From the stability studied, it was clear that the formulation was stable for thirty days resulting in no significant changes observed on drug release studies. It can be concluded that the jelly of piperine can be successfully prepared by using different concentration of polymer and thus, the problems of high half biological life, high bioavailability, lower clearance and lower elimination half-life can be overcome by formulating control release jelly. Hence control release drug delivery system is a useful dosage form for oral delivery of piperine. The piperine also having the various pharmacological activity like antioxidant ,anti-inflammatory, anti-hypertensive, neuroprotective, hepatoprotective, anti-depressant, and anticonvulsant etc.,

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