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Formulation and Evaluation of Paracetamol Tablets to Assess Binding Property of Orange Peel Pectin

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ABSTRACT

A matrix device, as the name implies, consists of drug dispersed homogenously throughout a polymer matrix. Matrix tablet it's the type of tablet which is designed such that it releases its contents regarding first-order kinetics or zero-order kinetics due to special arrangement and combination of hydrophobic and hydrophilic polymers as an excipient to form a matrix. Example of such matrix tablets are a controlled-release tablet, sustained released tablet. These all come under the category of modified-release tablet. Polymers have played indispensable roles in the preparation of pharmaceutical products. Their applications range widely from material packaging to fabrication of the most sophisticated drug delivery devices. In this formulation, the binding property of Orange peel pectin is assessed and evaluated with PCM tablets. In the present study, three different concentrations of pectin based matrix tablets were prepared by direct compression method. The powder of orange peel was found to have very good flow properties and was further used for tablet formulation. Paracetamol is used to treat many conditions such as headache, muscle aches, arthritis, backache, toothaches, colds, and fevers. It relieves pain in mild arthritis but does not affect the underlying inflammation and swelling of the joint. Binders are agents employed to impart cohesiveness to the granules. This ensures the tablet remains intact after compression especially in case of matrix tablets, the requirement for herbal mucoadhesives as matrix agents are gaining worldwide acceptance gradually.

INTRODUCTION

Polymers are macromolecules that display a dramatic physicochemical change in response to small changes in their environment. Smart polymer-based injectable formulations are easy to prepare and form implants at the site of injection upon administration. Smart polymers can be classified according to the external stimulus they respond to (temperature, pH, solvent, magnetic field, ions, and pressure). The development of smart polymer-based injectable drug delivery systems has gained attention over the past few years. This interest has been sparked by the advantages these delivery systems possess, which include ease of application, localized delivery for a site-specific action, prolonged delivery periods, decreased body drug dosage with a concurrent reduction in possible undesirable effects common to most forms of systemic delivery the nontoxic degradability, and improved patient compliance and comfort.

Polymers have played indispensable roles in the preparation of pharmaceutical products. Their applications range widely from material packaging to fabrication of the most sophisticated drug delivery devices. This review includes various polymers used in pharmaceutics based on their applications. The review focuses on the use of pharmaceutical polymer for controlled drug delivery applications. Examples of pharmaceutical polymers and the principles of controlled drug delivery are outlined and applications of polymers for controlled drug delivery are described. The field of controlled drug delivery is vast therefore this review aims to provide an overview of the applications of pharmaceutical polymers. General pharmaceutical applications of polymers in Dental Medicine, Ophthalmic Drug Delivery, Gene Delivery, Preparation of microspheres, etc. are also discussed briefly **(**Jagdeep et al., 2013)

Matrix Tablet

Matrix tablet it's the type of tablet which is designed such that it releases its contents regarding first-order kinetics or zero-order kinetics due to special arrangement and combination of hydrophobic and hydrophilic polymers as an excipient to form a matrix. Example of such matrix tablets is a controlled-release tablet, sustained released tablet. These all come under the category of modified-release tablet.

Matrix tablet is a promising approach for the establishment of extended and controlled release drug therapy as tablets offer the lowest cost approach to sustained and controlled release solid dosage forms. Matrix tablets may be defined as the oral solid dosage forms in

which the active ingredient is homogeneously dispersed throughout the hydrophilic or hydrophobic matrix (as shown in which serves as release rate retardants procedures such as coating and pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the formulation. These systems release drug in a continuous manner by diffusion-controlled and dissolution controlled mechanisms. Under gastric pH conditions, matrix tablet slowly erodes. Matrix tablets as the sustained release have given a new invention for a novel drug delivery system in the field of pharmaceutical technology. (Khatri et al., 2013)

A matrix device, as the name implies, consists of drug dispersed homogenously throughout a polymer matrix as represented in fig. 1. In this model, drug in the outer layer exposed to the bathing solution is dissolved first and then diffuses out of the matrix. This process continues with the interface between the bathing solution and the solid drug moving toward the interior. Derivation of the mathematical model to describe this system involves the following assumptions:

(1) A pseudo-steady state is maintained during drug release;

(2) The diameter of the drug particles is less than the average distance of drug diffusion through the matrix;

(3) The bathing solution provides sink condition at all times; and

(4) The diffusion coefficient of the drug in the matrix remains constant (i.e., no change occurs in the characteristics of the polymer matrix.

The equations presented below, which describe the rate of release of drugs dispersed in an inert matrix system, have been derived by Higuchi. The following equation can be written based on.

$$\frac{dM}{dh} = C_0 dh - \frac{C_S}{2} \qquad \text{---- (1)}$$

Where,

dM = change in the amount of drug released per unit area,

dH = change in the thickness of the zone of a matrix which has been depleted of drug,

C_o = total amount of drug in a unit volume of the matrix,

C_s = saturated concentration of the drug within the matrix.

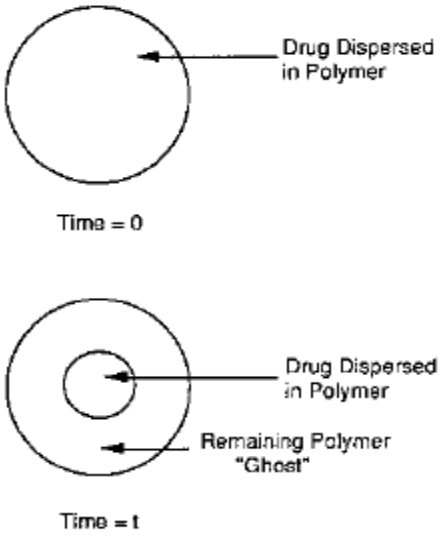


Figure No. 1: Matrix diffusion system before drug release (time = 0) and after partial drug release (time = t).

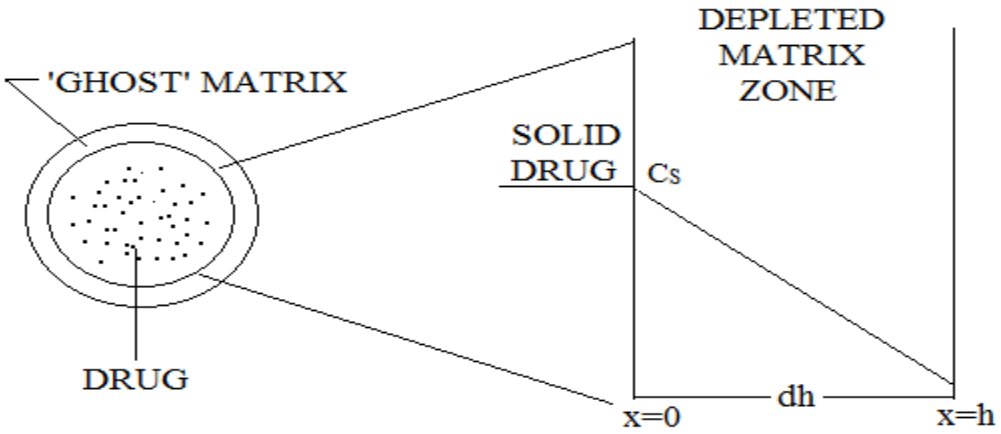


Figure No. 2: Schematic representation of a matrix release system. $C_s$is the saturation concentration of drug controlling the concentration gradient over the distance, h, of the remaining ghost matrix.

From diffusion theory,

$$dM = \frac{D_m C_s}{h} dt \qquad \text{---- (2)}$$

Where D_m is the diffusion coefficient in the matrix. Equating eqs. (5) and (6), integrating, and solving for h gives

$$M = [C_s D_m (2C_0 - C_s) t]^{1/2} \qquad \text{---- (3)}$$

When the amount of drug is more than the saturation concentration, that is, $C_{0>>}C_s$

$$M = (2 C_s D_m C_0 t)^{1/2} \qquad \text{---- (4)}$$

Which indicates that the amount of drug released is a function of the square root of time. Similarly, the drug release from a porous or granular matrix can be described by

$$M = \left[D_s C_a \frac{p}{T} (2 C_0 - p C_a) t \right]^{1/2} \qquad \text{---- (5)}$$

Where,

P = porosity of the matrix

T = tortuosity

C_a = solubility of the drug in the release medium

D_s = diffusion coefficient in the release medium

This system is slightly different from the previous matrix system in that the drug can pass out of the matrix through fluid-filled channels and does not pass through the polymer directly.

For purposes of the data treatment, Eq. (4) or (5) can be reduced to

$$M = kt^{1/2} \qquad \text{---- (6)}$$

Where k is a constant so that a plot of the amount of drug released versus the square root of time will be linear if the release of drug from the matrix is diffusion controlled. If this is the

case, then by the Higuchi model, one may control the release of drug from a homogeneous matrix system by varying the following parameters:

(1) The initial concentration of drug in the matrix,

(2) Porosity,

(3) Tortuosity,

(4) Polymer system forming the matrix, and

(5) The solubility of the drug.

Matrix system offers several advantages. They are, in general, easy to make and can be made to release high-molecular-weight compounds. Since the drug is dispersed in the matrix system, accidental leakage of the total drug component is less likely to occur, although in some cases, cracking of the matrix material can cause unwanted release. The primary disadvantages of this system are that the remaining matrix "ghost" must be removed after the drug has been released. Also, the release rates generated are not zero-order since the rate varies with the square root of time. A substantial sustained effect, however, can be produced through the use of very slow release rates, which in many applications are indistinguishable from zero-order.

These are the type of controlled drug delivery system, which continuously releases the drug. This release the drug by both dissolution controlled as well as diffusion-controlled mechanism. This control the release of the drug, which has different solubility properties, the drug is dispersed in swellable hydrophilic substance. An insoluble matrix of rigid nonswellable hydrophobic materials or plastic materials. (Gwen et al., 1996)

Advantages of Matrix Tablet

1. Easy to manufacture

2. Versatile, effective and low cost

3. Can be made to release high molecular weight compounds

4. The sustained-release formulations may maintain therapeutic concentrations over prolonged periods.

5. The use of sustain release formulations avoids high blood concentration.

6. Sustain release formulations have the potential to improve patient compliance.

7. Reduce the toxicity by slowing drug absorption.

8. Increase the stability by protecting the drug from hydrolysis or other derivative changes in the gastrointestinal tract.

9. Minimize the local and systemic side effects.

10. Improvement in treatment efficacy.

11. Minimize drug accumulation with chronic dosing.

12. Usage of the less total drug.

13. Improvement of the bioavailability of some drugs.

14. Improvement of the ability to provide special effects.

Disadvantages of Matrix Tablet

1. The remaining matrix must be removed after the drug has been released.

2. The high cost of preparation.

3. The release rates are affected by various factors such as food and the rate transit through the gut.

4. The drug release rates vary with the square root of time. Release rate continuously diminishes due to an increase in diffusional resistance and/or a decrease in the effective area at the diffusion front. However, a substantial sustained effect can be produced through the use of very slow release rates, which in many applications are indistinguishable from zero-order. (Patel et al ., 2011)

Table No. 1: Classification of matrix tablets

(A)Based on retardant materials used	(B) Based on the porosity of the matrix used
Hydrophobic matrices	Macro porous system
Lipid matrices	Microporous system
Hydrophilic matrices	Non-porous system
Biodegradable matrices	
Mineral matrices	

Table No. 2: Polymer used in matrix tablets

Hydrogel	Soluble polymer	Biodegradable polymer	Non-biodegradable polymer	Mucoadhesive polymer	Natural gum
Polyvinyl pyrrolidone	Polyvinyl alcohol	Polylactic acid	Ethylcellulose	Tragacanth	Kraya gum
Polyacrylamide	Hydroxypropyl methylcellulose	Polyanhydride	Polyvinyl chloride	Pectin	Guar gum

Drug Profile

Paracetamol

Paracetamol is widely used over the counter analgesic (pain reliever) and antipyretic (reduce fever). Paracetamol also known as acetaminophen, chemically named N-acetyl-p-aminophenol, is a widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer). Acetaminophen is the name adopted for this pharmacologic agent in the U.S. and Japan. Paracetamol is approved in a variety of international venues. Common trade names in English-speaking markets are Tylenol and Panadol.

Paracetamol is classified as a mild analgesic. It is commonly used for the relief of headaches and other minor aches and pains and is a major ingredient in numerous cold and flu remedies. In combination with opioid analgesics, paracetamol can also be used in the management of more severe pain such as post-surgical pain and providing palliative in care for advanced cancer patients. Though paracetamol is used to treat inflammatory pain, it is not generally classified as an NSAID because it exhibits only weak anti-inflammatory activity.

Paracetamol is used to treat many conditions such as headache, muscle aches, arthritis, backache, toothaches, colds, and fevers. It relieves pain in mild arthritis but does not affect the underlying inflammation and swelling of the joint. (Seetha Devi., 2013)

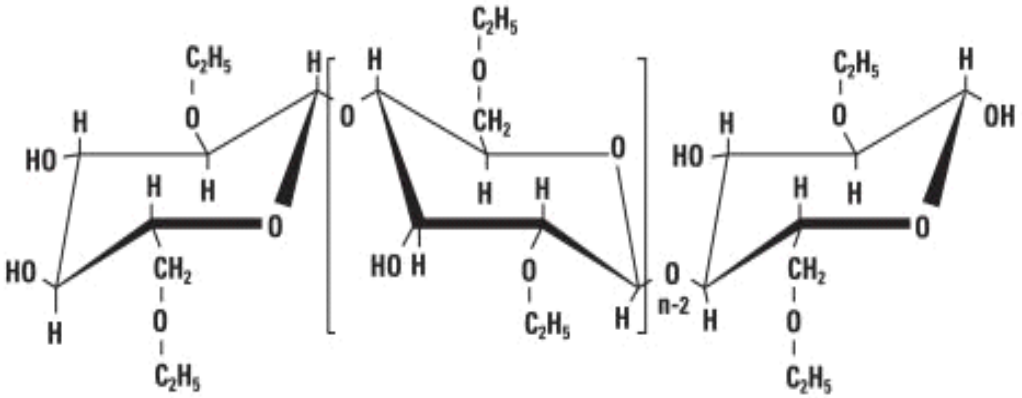
Mechanism of action

The mechanism by which paracetamol reduces fever and pain is debated largely because paracetamol reduces the production of prostaglandins (pro-inflammatory chemicals). Aspirin also inhibits the production of prostaglandins, but, unlike aspirin, paracetamol has little anti-inflammatory action. Likewise, whereas aspirin inhibits the production of the pro-clotting chemicals thromboxanes, paracetamol does not. Aspirin is known to inhibit the (COX) family of enzymes and because of paracetamol's partial similarity of aspirin's action; much research has focused on whether paracetamol also inhibits COX. It is now clear that paracetamol acts via at least two pathways. The COX family of enzymes is responsible for the metabolism of arachidonic acid to prostaglandin H_2, an unstable molecule, which is, in turn, converted to numerous other pro-inflammatory compounds. Classical anti-inflammatory, such as the NSAIDs, block this step. Only when appropriately oxidized is the COX enzyme highly active. Paracetamol reduces the oxidized form of the COX enzyme, preventing it from forming pro-inflammatory chemicals. (Seetha Devi., 2013)

Polymer Profile

Synthetic polymer

Ethyl Cellulose:



Chemical Formula: $(C_{10}H_{18}O_5)$ n

Other Names: Aquacoat, Cellulose ethyl ether, E462, Ethocel, Surelease.

Structure: Solid.

Density: 0.4 gm/cm^2.

Glass transition temperature: 129-133^{0}C

Specific gravity: 1.12-1.15 gm/cm^3.

Ethylcellulose in granule form to be used in controlled – release matrix formulations. Partly O-ethylated cellulose, it contains 44-51% ethoxy group calculated on the dried basis.

Physical character: White to yellowish-white in color, odorless, free-flowing white to light tan powder or granular powder. Its aqueous suspension is neutral to litmus.

Solubility: Freely soluble in dicyclomethane, ethanol, methanol, toluene, ethyl acetate. Practically insoluble in water, glycerol, and polyethylene glycol. Ethyl cellulose-containing 46.5% or more ethoxy group is freely soluble in alcohol, in chloroform, in ethyl acetate, in methyl alcohol, and toluene. Its aqueous solution is neutral to litmus.

Loss of drying: If dried at 105°C for 2 hours, it loses only 3% of its weight. In the present study, ethylcellulose used was having an ethoxy content of 47.5% by weight and viscosity of 14 cps in a 5% concentration. By weight in an 80:20 toluene ethanol solution at 25°C.

Suitability of ethylcellulose for sustained release formulation:

a) Availability in a wide range of viscosity or molecular weight grade.

b) Solubility in a variety of organic solvents.

c) Miscibility with various water-soluble materials that permit the permeability characteristics of matrix film to be readily changed.

d) Cost is comparatively less than other polymers.

Ethylcellulose has been used as the retardant polymer in controlled release dosage forms. Ethylcellulose reduces the drug release due to a reduction in the penetration of the solvent

molecules into the system because of the hydrophobic nature of ethylcellulose present on the surface of the tablets i.e.; the rate of release is controlled by the permeability of matrix structure.

Uses: Ethylcellulose is used as a binder in tablets and as a coating material for tablets, in granules and microcapsules. It is also used as a thickening agent. (Roy et al., 2012)

Plant profile

Orange peel:

Figure No. 3: *Citrus aurantium* peels and tree

Table No. 3: Taxonomy classification

Kingdom	Plantae
Subkingdom	Tracheobionta
Superdivision	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Subclass	Rosidae
Order	Sapindales
Family	Rutaceae
Genus	Citrus L.

Table No. 4: Vermicular name

Hindi	Narangi
English	Orange
Tamil	Naaram
Malayalam	Naaranga
Telugu	Narinja
Punjabi	Satara
Kannada	Kittale
Marathi	Santra

Biological source: It consists of fresh fruit of *Citrus aurantium.*

Family: Rutaceae

Chemical constituents: It contains Pectin, Limonene, Carveol, Carvone.

Uses:

- Pectin used for high cholesterol, high triglycerides, and to prevent colon cancer and prostate cancer.

- It is also used for diabetes and gastroesophageal reflux disease (GERD). Some people use pectin to prevent poisoning caused by lead, strontium, and other heavy metals.

- Pectin was used for years in combination with kaolin (Kaopectate) to control diarrhea.

Review of Literature

1. **Srivastava et al. (2010)** study formulation and evaluation of a paracetamol tablet to assess the binding property of orange peel pectin. Extract pectin from dried orange peel to assess its binding property in tablet using paracetamol as model drug initially orange fruit peel powder was subjected to simple water-based soxhlet extraction and pectin was isolated using ethyl alcohol as the precipitating agent. Thereafter, four batches were formulated using pectin in different proportions. A reference batch of starch was also prepared to carry out the comparative study and to assess the binding property of pectin. Precompression and post-compression studies were performed for each formulation. *In-vitro* release data were subjected to the application of various kinetic models. The results obtained for all pre-

compression and post-compression parameters were found within an acceptable range of pharmacopeias. Based on drug release behavior, it can be summarized that the release of all four batches understudy was less than that of reference batch. Orange peel pectin can act as an excellent binder in dosage forms. Since it is of natural origin and orange peels available at low cost it may prove to be better binder over commercial used synthetic pectin.

2. **Jain et al. (2008)** studies in preparation and evaluation of sustained release matrix tablet of furosemide using natural polymer. Sustained-release tablets of furosemide were fabricated using pectin, guar gum, and Xanthan gum. The tablets were evaluated for physical characteristics like hardness, weight variation, friability, and drug content. In-vitro release of drug was performed in PBS pH 7.2 for fifteen hours. All the physical characters of the fabricated tablet were within acceptable limits. The tablet with guar gum exhibited greater swelling index than those with pectin and Xanthan gum. A better-controlled drug release (80.74%) was obtained with the matrix tablet (G4) made-up of the guar gum than with the pectin and Xanthan gum. It is cleared through the dissolution profile of furosemide from matrix tablets prepared using different natural polymer retarded approx 15hrs.

3. **Khule et al. (2012)** study the extraction of pectin from the citrus fruit peel and use as a natural binder in paracetamol tablet. Extract pectin from dried citrus fruit peels. To increase profits for citrus fruit growers and processors, citrus fruit peels, a by-product of citrus fruit processing, were investigated as a source of pectin. Pectin extraction was optimized from this by-product. Pectin was extracted under pH 2; Ethanol ratios(ER) 1:1 and extraction periods 120 min, at this condition the highest yield was obtained 18.21%. Pectin assesses its binding property in tablets using paracetamol as a model drug. Thereafter, four batches were formulated using pectin in different proportions. A reference batch of starch was also prepared to carry out the comparative study and to assess the binding property of pectin. Pre-compression and post-compression studies were performed for each formulation and compared to the range as per pharmacopeias. In vitro dissolution studies revealed that batch M3 showed 81.88% drug released. In-vitro release kinetic of all four batches followed Korsmeyer- peppas models. Citrus peel pectin can act as an excellent binder in dosage forms. Since it is of natural origin and citrus peels available at low cost it may prove to be better binder over commercially used synthetic binders.

4. **Rao et al. (2009)** study on formulation and evaluation of sustained release matrix tablet of tramadol hydrochloride. The objective of the present work was to develop sustained

release matrix tablets of water-soluble Tramadol hydrochloride using different polymers viz. hydroxypropyl methylcellulose (HPMC) and natural gums like Karaya gum (KG) and Carrageenan (CG). Varying ratios of drug and polymer-like 1:1 and 1:2 were selected for the study. After fixing the ratio of drug and polymer for control the release of the drug up to desired time, the release rates were modulated by a combination of two different rates controlling material and the triple mixture of three different rates controlling material. After evaluation of physical properties of tablet, the *in vitro* release study was performed in 0.1N HCl pH 1.2 for 2 hrs and phosphate buffer pH 6.8 up to 12 hrs. The effect of polymer concentration and polymer blend concentration were studied. Different ratios like 80:20, 60:40, 50:50, 40:60 and 20:80 were taken. Dissolution data was analyzed by Korsmeyer-Peppas power-law expression and modified power-law expression. It was observed that matrix tablets contained polymer blend of HPMC/CG were successfully sustained the release of drug up to 12 hrs. Among all the formulations, formulation F16 which contains 20% HPMC K15M and 80% of CG release the drug which follows Zero-order kinetics via, swelling, diffusion and erosion and the release profile of formulation F16 was comparable with the marketed product. Stability studies (40±2ºC/75±5%RH) for 3 months indicated that Tramadol hydrochloride was stable in the matrix tablets. The DSC and FTIR study revealed that there was no chemical interaction between drug and excipients.

5. **Devi et al. (2013)** studied on formulation and evaluation of diclofenac sodium matrix tablets using Abelmoschus esculentus mucilage as a polymer. Preparation and evaluation of diclofenac sodium controlled release matrix tablets using various proportions of natural polymer *Abelmoschus esculentus* mucilage powder as release controlling factor by Wet Granulation method. The tablets were evaluated for various parameters like friability, weight variation, hardness, drug time, content uniformity. *In vitro*, drug release characteristics of dosage form were evaluated in 6.8 pH phosphate buffer. All the formulations followed zero-order kinetics along with diffusion mechanisms. *In vitro* release data, formulation F4 containing Drug: Polymer (1:1.5) showed maximum drug release of 99.8%. All the formulations F1 to F5 undergo non-Fickian diffusion or Anomalous diffusion mechanism. Analysis of drug release rate from the matrix system indicated drug was released by the super case-II transport mechanism.

Need and Plan of Work

Binders are agents employed to impart cohesiveness to the granules. This ensures the tablet remains intact after compression especially in case of matrix tablets, the requirement for herbal mucoadhesives as matrix agents are gaining worldwide acceptance gradually. The excipient industry in developing on a large scale and herbal hydrocolloids can act as an important contributor. The researchers are in constant search for new excipients for potential use as binding, matrixing agent in sustained release tablet formulations, which need to be inert, non-toxic, biocompatible and biodegradable. This is because different binding/matrixing agent can be useful in achieving various tablet mechanical strength & drug release properties for different pharmaceutical purpose. Natural binders like different starch, gums, mucilage, dried fruits possess binding capacity as well as some other properties like filler, disintegrant & natural polymers are safe & economical than polymers like PVP.

Plan of Work

1	Collection of plant material (peels of orange fruit)	
2	Selection and procurement of drug namely Paracetamol	
3	Preparation of mucilage by the extraction procedure	
4	Preparation of paracetamol tablets	
5	Evaluation test parameter	Weight variation
		Hardness
		Friability
		Thickness
		Drug content

MATERIALS AND METHODS

Requirements

Table No. 5: List of instruments

Sr. No.	Particular	Company Names
1	Electronic balance	Digital Scales, China
2	Tablet punching machine	Madhur Engineering works, India
3	Water bath	Sonar Engineering works, India
4	Dissolution apparatus	Lab India, India
5	Friability apparatus	Sonar Engineering works, India
6	Monsanto hardness tester	Monsanto, USA
7	Rotary vacuum evaporator	HS2000, Korea rotary evaporator, Korea

Table No. 6: List of glassware

Sr. No.	Particular	Quantity
1	Beaker	500ml, 1000ml
2	Measuring cylinder	50ml, 500ml
3	Conical flask	1000ml
4	Pipette	50ml

Table No. 7: List of chemical

Sr. No.	Particular	Company name
1	Paracetamol	S.D. Fine, India
2	Sucrose	Central Drug House, India
3	Ethylcellulose	Central Drug House, India
4	MCC	Central Drug House, India
5	Starch	Central Drug House, India
6	Magnesium stearate	Central Drug House, India
7	HCl	Ranked, India
8	Ethanol	S.D. Fine, India

Collection of plant materials

The plant and peel of orange are collected from the local market of Dehradun.

Extraction procedure *Citrus aurantium* peels

- Dried Orange fruit peel powder (200g) was used for extraction using soxhlet apparatus.
- The water to be used for extraction was acidified using 0.5N citric acid and pH was maintained about 2.
- The content of the round bottom flask was heated continuously at 75º C for around 7 to 8 hr after the start of the first siphon cycle.
- The proportion of powder to solvent was taken in ratio 1:6. After the heating period was over, the mixture was passed through a twofold muslin cloth and was cooled to room temperature.

Isolation of pectin

- Isolation of pectin was carried out using ethyl alcohol as a precipitating agent.
- Ethyl alcohol was used as a precipitating agent for pectin. For this purpose, twice amount of ethyl alcohol was added to the cooled solution and continuous stirring was done for 15 min.
- Then the mixture was kept aside for 2hr without stirring. Pectin was filtered through a four-layered muslin cloth.
- The precipitate was washed 2 to 3 times by ethyl alcohol, to further remove any remaining impurity.
- Finally, the precipitate was kept for drying at 35ºC to 40ºC in hot air oven, It was then stored in desiccators until further use. (Srivastava Praniti., 2010)

Table No. 8: Formulation and preparation of Paracetamol matrix tablets

Ingredients	Quantity in mg		
	FF1	FF2	FF3
Drug	200	200	200
Ethylcellulose	80	50	20
HCDs	20	50	80
Magnesium stearate	3	3	3
Talc	3	3	3
MCC	154	154	154
Starch	40	40	40

Procedure

- The tablets of paracetamol were prepared by direct compaction method by using suitable blends of ethyl cellulose and Selected HCD used as the matrix forming polymers.
- MCC was used as a diluent,
- Each fabricated formulation was composed of drug and excipients in various proportions. For the formulation of tablets all the ingredients were passed through sieve #20 and were collected and mixed well to get a uniform mixture.
- Magnesium stearate and talc were added as a lubricant and the granules were composed into matrix tablets using a hand-operated single tablet punching machine (Roy et at ., 2012).

3. Evaluation Parameters of Matrix Tablets

Tablets were evaluated for their characteristic parameter, such as

(A) Weight variation

Twenty tablets selected randomly and were weighed accurately. The average weight of the tablets was calculated. Then the deviation of individual weight from the average weight was determined. All values were expressed by mean± standard deviation.

Table No. 9: Weight variation limits for tablets as per IP (2010)

Sr. No.	The average weight of the tablet	% Deviation
1.	80 mg or >80	± 10
2.	≤80≥250	±7.5
3.	≤250	± 5

(B) Hardness

In the pharmaceutical industry, the mechanical strength is often referred to as the crushing strength or the hardness. It is dependent on the binding efficacy of the incorporated binder. Brook and Marshal have described hardness as "the compression forces that, when applied diametrically to tablets, just breaks". Many types of hardness testers are available like Stokes (Monsanto), Strong-cobb, Pfizer, Erweka and Schlesinger.

Randomly sampled five tablets from each batch were used for the determination of hardness with the help of Monsanto hardness tester.

(C) Friability

Friability is also called as the test for abrasion or mechanical robustness. It can be calculated as,

$$\% \text{ Loss} = \frac{\text{Initial wt. of tablet} - \text{final wt. of tablet}}{\text{Initial wt. of tablet}} \text{ x } 100$$

The friability test was done using Roche's friabilator. Twenty tablets were selected randomly and weighed individually. Then the friability test was carried out at 25 rpm for 4 minutes. These tablets were then again weighed and the percentage loss in weight was calculated.

(D) Thickness

The individual crown-to-crown thickness of ten tablets from each batch was determined using slide caliper.

(E) Drug content

The tablets were powdered, and 500 mg equivalent weight of Paracetamol in tablet powder was accurately weighed and transferred into a 100 ml volumetric flask. Initially, 10 ml of

phosphate buffer (pH7.4) was added and shaken for 10 min. Thereafter, the volume was made up to 100 ml with buffer. Subsequently, the solution in the volumetric flask was filtered, and 1 ml of the filtrate was diluted and analyzed at 247nm using UV visible spectrophotometer. (Shimadzu UV-2450, Japan) (Roy et al., 2012)

RESULTS AND DISCUSSION

As per the data obtained by the experiment, pectin derived from orange peel showed a good binding property. The prepared tablets for a post-compression parameter such as weight variation, hardness, friability, in vitro dissolution study and thickness. The readings were obtained and values were presented. Weight variation among all the tablets range between 0.4019 to 0.4036gm, hardness values which were obtained within a limited range from 5.50kg/cm^2 to 5.80kg/cm^{2,} the thickness of all the tablets range between 3.76mm to 3.80mm, friability of the entire batch in less than 1%.

Table No. 10: Observation table

Parameter	FF1	FF2	FF3
Wt. variation(gm)	0.4031	0.4019	0.4036
Hardness(kg/cm^2)	5.50	5.80	5.60
Friability (%)	0.51	0.499	0.427
Thickness(mm)	3.76	3.78	3.80
Drug content(mg)	496.4	498.2	496.9

Among these parameters, all were within specified official limits. This indicates that there shall not be any problem while formulating tablet dosage form using orange peel derived pectin as a matrix agent.

CONCLUSION

In the present study, three different concentrations of pectin based matrix tablets were prepared by direct compression method. The powder of orange peel was found to have very good flow properties and was further used for tablet formulation. The formulation of matrix tablet prepared was found to pass all the evaluation parameters including weight variation, friability, hardness, thickness showing that the orange peel can be successfully used in the preparation of matrix formulation. Simple water-based extraction is an efficient method for

extracting pectin from orange peel powder. Also, a major conclusion can be derived based on the above experiment that orange peel pectin which is a polymer of natural origin, has immense potential to replace the commercially existing polymers used as matrix agent in tablet dosage forms.

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