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Formulation And Evaluation Of Binding Properties Of Pectin Isolated From *Daucus carota* And *Vicia faba* In Anastrozole Capsule

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Abstract : This investigation explores the efficacy of natural pectin derived from carrot peels and legumes as a pharmaceutical excipient in the formulation of Anastrozole tablets. Pectin, a polysaccharide recognized for its gelling and thickening capabilities, was extracted through a standardized protocol and subsequently characterized in terms of its physical and chemical attributes. The suitability of the extracted pectin as a binder and disintegrant in tablet formulations was rigorously assessed.

A series of Anastrozole tablet formulations were developed, incorporating varying concentrations of pectin sourced from both carrot peels and beans. The resulting tablets were subjected to comprehensive physicochemical evaluations, including assessments of hardness, friability, disintegration time, and drug release profiles. Preliminary findings suggest that both natural pectin sources demonstrated commendable binding and disintegration properties, with formulations exhibiting significantly enhanced drug release parameters compared to those utilizing traditional excipients.

This study underscores the potential of employing natural pectin from carrot peels and beans as a sustainable alternative in the preparation of Anastrozole tablets, thus contributing to the advancement of more efficacious and patient-centric pharmaceutical formulations. Future research endeavours are recommended to optimize the extraction methodologies and to investigate the long-term stability of these formulations.

KEYWORDS: Pectin, binding agent, anastrozole, carrot peels and beans.

1.INTRODUCTION

A binder is a crucial substance in pharmaceuticals for granulation and tablet formation, with common examples being starch, polyethylene glycol (PEG), and hydroxypropyl methylcellulose (HPMC). Pectin, a plant polysaccharide, comprises 0.5% to 4% of a plant's dry mass and is found in high-pectin fruits like apples, citrus, quinces, and berries. Types of pectin include: High Methoxyl (HM) Pectin: Requires sugar and acidity for gelation, ideal for jams. Low Methoxyl (LM) Pectin: Gels with calcium, suitable for low-sugar products.

Pectin has culinary applications in thickening, stabilizing beverages, and enhancing confections. It also acts as a soluble fibre that aids digestion, manages cholesterol, and regulates blood sugar. Emerging sources of pectin, such as carrot peels and beans, may benefit the pharmaceutical industry.

Lactose, a milk sugar, is digested by lactase. Lactose intolerance can occur due to low lactase levels and may cause bloating and diarrhoea. Types include primary (genetic), secondary (gastrointestinal issues), and congenital (absence of lactase). Management includes lactase supplements and dairy alternatives.

Carboxymethyl cellulose (CMC) is a cellulose-derived polymer known for its thickening properties, used in food, pharmaceuticals, cosmetics, and textiles. It is biodegradable but may cause bloating or allergies.

Starch, a glucose polysaccharide for energy storage in plants, consists of amylose (20-30%) and amylopectin (70-80%), found in cereals and root vegetables. It is used as a thickener in cooking and in biodegradable plastics.

Anastrozole, sold as Arimidex®, is an oral aromatase inhibitor for treating hormone receptor-positive breast cancer in postmenopausal women. It reduces oestrogen levels and has possible side effects like hot flashes and fatigue. It is contraindicated in certain populations and requires proper storage to maintain efficacy. Developing a natural pectin-based capsule could enhance its bioavailability.

2.NEED OF THE STUDY.

To assess the binding characteristics of pectin from carrot and broad beans in Anastrozole tablet formulations and compare its efficacy as a natural binder to traditional excipients. Primary Objectives are Isolate and characterize the physicochemical properties of carrot and broad bean pectin. Evaluate the binding efficacy of the isolated pectin in Anastrozole tablets. Compare the binding properties of carrot and broad bean pectin with commercial pectin. Investigate the effect of different pectin concentrations on binding in Anastrozole tablets. Assess the influence of varying compression forces on the binding performance of pectin-formulated tablets. Analyze the physical and mechanical properties of Anastrozole tablets containing carrot and broad bean pectin.

3.RESEARCH METHODOLOGY

The methodology section outline the plan and method that how the study is conducted. This includes Universe of the study, sample of the study, Data and Sources of Data, study's variables and analytical framework. The details are as follows;

3.1 Evaluation of Pectin from Daucus carota (Carrot) & Vicia faba (Broad Beans)

Materials: Sodium Hydroxide (NaOH), Hydrochloric Acid (HCl), Pectin, Carboxy Methyl Cellulose (CMC), Ethanol, Lactose, Starch, Carrots, Broad Beans.

Preparation of Peels: Carrot and broad bean peels were washed, chopped, sun-dried for 24 hours, and air-dried for 72 hours until constant weight. They were then milled and stored in an airtight container.

Preparation of 0.1N HCl: 1 ml of concentrated HCl was diluted to 100 ml with distilled water.

3.2 Extraction of Pectin:

Dried peel powder was dissolved in 300 ml deionized water with HCl and NaOH, heated at 90°C for 1 hour, and filtered. The residue was treated with water and adjusted with HCl and NaOH. The resulting filtrate was mixed with ethanol (1:2 ratio) and allowed to stand for 12 hours. The pectin was then filtered, washed, dried, and milled, with percentage yield calculated.

3.3 Organoleptic Properties:

The colour, taste and smell of the extracted pectin powder were assessed by 5 persons, and the consensus attribute accorded by a majority of three persons for an organoleptic parameter was recorded.

3.4 FTIR Analysis:

The extracted pectin powder as well as pectin BP were subjected FTIR analysis. Using the potassium bromide (KBr) pellet method, 100 mg of KBr was weighed and mixed uniformly with 5 mg sample in fine particle size state. The mixed sample was placed in an evacuable KBr die of a hydraulic press and compressed into a pellet. Pelletized sample was placed in a cell holder and inserted into the FTIR machine (FTIR-4100 Spectrophotometer , shimadzu Co. Japan) and scanned at a range of 750-4000 cm-1

3.5 Formulation of Anastrozole Granules:

Anastrozole granules were prepared using the wet granulation method based on a specified formula.

Ingredients(mg)	**Batches**				
	A	**B**	**C**	**D**	**E**
Anastrozole	500mg	500mg	500mg	500mg	500mg
Lactose	60mg	60mg	60mg	60mg	60mg
Starch	15mg	15mg	15mg	15mg	15mg
Carrot peel pectin+bean peel pectin	5.8mg	18mg	20mg	_	_
CMC	_	_	5.8mg	18mg	20mg
Pectin	_	_	5.8mg	18mg	20mg

Table 1: Formula of prepared Anastrozole powder blends and capsules

Five batches of granules were prepared using different binder solutions (carrot peels, broad bean peel, pectin, or carboxymethyl cellulose) to produce 50 capsules per batch. The wet mass, which included anastrozole, lactose, and starch, was dried at 50°C for 6 hours, milled, and sieved before storage in an airtight container. Micromeritic Properties of Anastrozole Granules

3.6 Micromeritic properties of Anastrozole granules:

3.6.1. Granule Density:

Determined using the pycnometer method by weighing 2-3 grams of dried granules after drying at 105°C for 2 hours. The density is calculated based on the mass and volume of the granule-water mixture.

$$\text{Density} = \frac{weight\ of\ granuels}{volume\ of\ granule - water\ mixture - weight\ of\ water} \quad (1)$$

3.6.2 Angle of Repose:

Measured by allowing granules to fall freely from a funnel onto a surface, with the height and diameter of the cone used to calculate the angle.

$$\text{Angle of repose } (^0) = \tan\theta \frac{h}{r} \quad (2)$$

3.6.3 Flow Rate:

Assessed using the fixed funnel method, recording the time taken for 50 grams of granules to flow through.

$$\text{Flow rate} = \frac{weight\ of\ granules\ (g)}{time\ of\ flow(sec)} \quad (3)$$

3.7 Drug-Excipient Interactions:

Investigated through FTIR analysis to study compatibility between Anastrozole and extracted pectin powders, using pure samples and granules prepared with a specific concentration of pectin solution.

3.8 Filling of Granules into Gelatin Capsule Shells:

Approximately 500 mg of granules were hand-filled into empty gelatin capsules. The closed capsules were wiped with a soft cloth to remove any residual powder and then stored in airtight transparent bags with silica gel for further analysis.

3.9 Evaluation of Anastrozole Capsules:

3.9.1.Weight Variation:

Twenty capsules from each batch were weighed individually to calculate their mean weight and standard deviations using the BP method. Percentage variation was then determined.

$$\text{Percentage variation} = \frac{individual\ weight - average\ weight}{average\ weight} \times 100 \quad (4)$$

3.9.2.Disintegration Test:

Six capsules were tested using a disintegration apparatus with a liquid maintained at 37°C. Capsules were placed in the liquid, and the time taken for complete disintegration was recorded, along with the average and standard deviation.

3.9.3.Dissolution Test:

The dissolution test utilized the basket method according to USP standards. A capsule was immersed in 900 mL of 0.1 N HCl at 37°C, with a stirring speed of 120 rpm. Samples were taken at set intervals for 90 minutes, filtered, diluted, and their absorbance measured at 278 nm. Triplicate tests were conducted to compute the mean and standard deviation.

3.9.4. Brittleness Test:

To test the brittleness of hard gelatin capsules, first select a representative sample and condition them at 20-25°C and 40-50% RH for at least 24 hours. Use a brittleness tester by placing a single capsule on it and gradually applying a controlled force that simulates handling and transportation. Measure the load at which the capsule deforms and record the breaking point.

3.9.5.Moisture Test: Loss on Drying (LOD):

To ensure the integrity of hard gelatin capsules, conduct a moisture test. Weigh a sample of capsules accurately, noting the initial weight. Dry the capsules in a desiccator at approximately 60°C ± 5°C to remove moisture. After drying, cool the capsules in the desiccator to prevent reabsorption of moisture, then weigh them again and record the final weight.

$$\text{Moisture content (\%)} = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

4. RESULTS AND DISCUSSION

4.1 Phytochemical properties:

The phytochemical evaluation of powdered peels from Daucus carota and Vicia faba revealed the presence of alkaloids, flavonoids, saponins, terpenoids, polysaccharides, tannins, and carbohydrates, while anthraquinone and cardiac glycosides were absent.

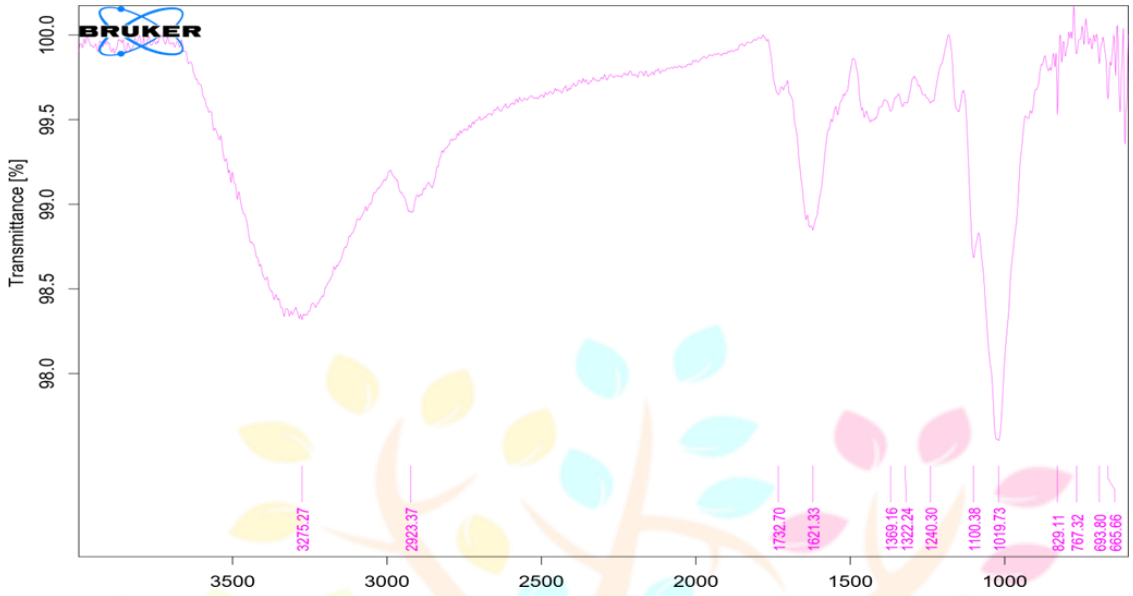
Parameter	Daucus corota	Vicia faba
Alkaloid	+	+
Anthraquinone	-	-
flavonoid	+	+
Saponin	+	+
Cardiac glycosides	-	-
Terpenoid	+	+
Polysaccharides	+	+
Tannin	+	+
Carbohydrate	+	+

Key: +(present), - (absent)

4.2 Percentage yield and organoleptic properties of extracted pectin:

For extracted pectin, the yield percentages were noted for Daucus carota and Vicia faba, both exhibiting a brown coloration and a bitter taste with distinct aromatic properties.

4.3 FTIR analysis of pectin:



4.4 Granule flow properties:

Granule flow properties for Anastrozole granules were analyzed, showing a decrease in volume attributed to particle size and shape. Carr's indexes and Hausner's ratios ranged from 1.12 to 1.33 and 11.11% to 32.61%, respectively. The angles of repose and flow rates ranged from 30.47° to 43.89° and 1.17 to 5.18 g/sec, indicating favorable flowability with plant-derived pectin.

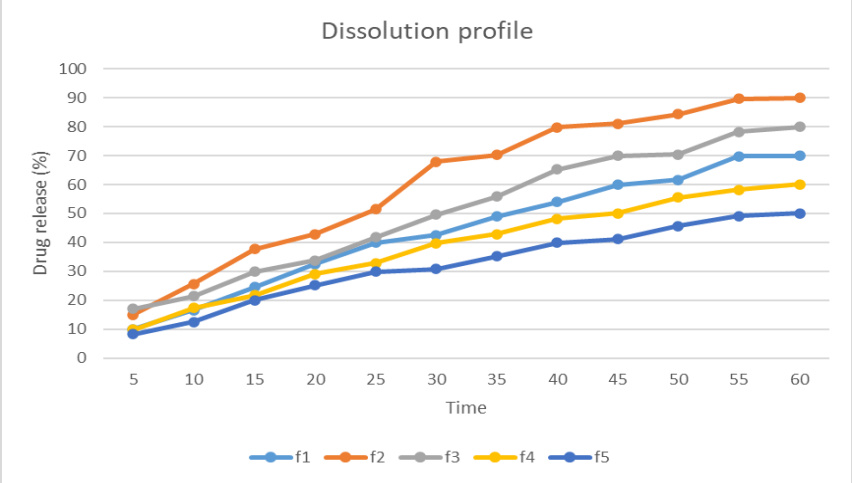
Batch	Granule density	angle of repose	Flow rate
A	0.43 ± 0.011	30.50 ± 0.023	4.18 ± 0.016
B	0.46 ± 0.010	35.03 ± 0.017	4.03 ± 0.014
C	0.36 ± 0.007	44.89 ± 0.013	2.78 ± 0.018
D	0.57 ± 0.016	36.64 ± 0.021	1.34 ± 0.015
E	0.47 ± 0.020	33.06 ± 0.012	2.75 ± 0.011

4.5 Physicochemical properties of anastrozole capsules:

Anastrozole capsules formulated with varying binder concentrations met weight uniformity standards set by the United States Pharmacopeia, while disintegration times ranged from 5.40 to 7.40 minutes across batches, complying with pharmacopoeial standards.

TIME	f1	f2	f3	f4	f5
5	10	15	17	9.8	8.2
10	16.5	25.6	21.4	17.3	12.4
15	24.5	37.6	29.9	21.7	19.9
20	32.5	42.9	33.7	29	25.1
25	39.8	51.5	41.8	32.8	29.8
30	42.6	67.9	49.5	39.7	30.7
35	48.9	70.2	55.8	42.9	35.1

40	53.9	79.8	65.3	48.1	39.9
45	59.9	81.1	69.9	50.1	41.1
50	61.6	84.3	70.4	55.6	45.7
55	69.7	89.7	78.2	58.2	49.1
60	70	90	80	60	50



4.6 Drug- excipient interactions:

The spectral analysis of pure anastrozole (a) shows characteristic bands that are also present in the spectra of granules formulated with pectin from carrot (b) and broad bean (c) peels. This indicates that the core molecular structure of anastrozole remains intact in the formulations. Furthermore, the lack of new peaks in the spectra suggests that no significant chemical reactions occurred during the incorporation of pectin into the dosage forms.

5. Conclusion:

The study successfully extracted and evaluated pectin from Carrot and Broad beans as a natural binder for anastrozole capsules. Results showed that increased binder concentration reduced drug release, with pectin demonstrating binding properties comparable to synthetic options like carboxymethyl cellulose. The pectin-based capsules passed various tests, including brittleness and disintegration, and showed no adverse interactions with the drug in FTIR analysis. Thus, pectin from these sources presents a viable alternative to traditional synthetic binders in capsule formulations.

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