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IBUPROFEN SUSTAINED RELEASE MATRIX TABLET FORMULATION AND CHARACTERIZATION USING NATURAL POLYMERS

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ABSTRACT

An innovative extended-release Ibuprofen formulation offers efficient once-daily treatment for osteoarthritis and rheumatoid arthritis. The current work describes the use of natural polymers such xanthan gum, gelatin, and pectin in the manufacture of an Ibuprofen matrix tablet. Physical characteristics of the tablets, including their drug concentration, hardness, weight fluctuation, and friability, were closely investigated and were determined to be within acceptable bounds. A comparative study showed that the swelling indices of the tablets containing distinctive natural polymers varied, and the tablets containing gelatin had distinct features. Ibuprofen was released in a controlled and prolonged manner, as seen by the release profile, this was particularly apparent in the gelatin matrix.

Conclusion: This study opens the door for applications in pharmaceutical formulations by emphasizing the potential of natural polymers when fabricating tablets with sustained-release Ibuprofen and offering insights into their unique release kinetics.

Keywords: Ibuprofen, Pectin, Gelatin gum, Xanthan gum, sustained release

INTRODUCTION:

Drug formulations designed to extend dosing intervals by regulating drug absorption have a longstanding history. Ongoing experiment explores the application of naturally occurring biocompatible polymers in crafting

controlled-release oral dosage forms. Natural gums, characterized by biodegradability and non-toxicity, swell when in contact with aqueous media, making them suitable for preparing drug formulations. For instance, drugs like isoniazid and diltiazem have been released under regulated conditions using matrix formers made of polysaccharide derivatives with glycoside linkage, such as gelatin **[1]**. Pectin, found in various ester and amidated forms, are globally employed in food and have demonstrated utility in building medication delivery systems with targeted release. Xanthan gum is an extracellular polysaccharide with a high molecular weight, shares a backbone with cellulose and is produced through the fermentation of Xanthomonas campestris. Initially used for thickening, suspending, and emulsifying water-based systems, and is a hydrophilic polymer **[2]**. Ibuprofen, a NSAID medication used to lower fever and ease minor pains and aches associated with menstruation, the common cold, headaches, muscle aches, arthritis, toothaches, and backaches which acts by inhibiting cyclooxygenase enzyme (COX) **[3]**.

Deformation lubricants prevent the powder or granules from sticking to the punch die or faces during compaction to enable their smooth ejection from the die. Lubricants can also be used in situations where compression is not necessary, like in powder blends that are filled into capsules **[4]**. They can be used to coat the surface of multi-particulate dosage forms to prevent the agglomeration of individual particles and to prevent granules or powder from adhering to equipment surfaces and dosator mechanisms **[5]**. The most common lubricants found in tablets or hard gelatin capsules are lipids like plant-based stearin, magnesium stearate, or stearic acid, and minerals like talc or silica. Hydrophobic lubricants constitute the most often used lubricants **[6]**. These typically work at significantly low concentrations, and many of them also have glidant and anti-adherent characteristics **[7]**.

When the therapeutic dosage in isolation is inadequate for imparting an adequate bulk for the tablet, diluents are fillers used to bridge the gap. The following uses of diluents in tablet formulation are also conceivable **[8]**.

- To render superior tablet attributes like increased solidarity
- Permitting the utilization of direct-compression manufacturing
- To encourage the powder or grains to flow

Due to the variety of diluents employed in tablet manufacture, variations in the physical characteristics and performance of the formulation are caused by these diluents **[9]**. Additionally, the diluent concentration

in the formulation is crucial as it can alter the final formulation's qualities, particularly in terms of the tablet compression and release qualities **[10]**.

The intention of this research is to create ibuprofen tablets with prolonged release by using natural polymers like pectin, xanthan gum, and gelatin gum. An cutting-edge extended-release ibuprofen formulation offers efficient once-daily medication for the management of osteoarthritis and rheumatoid arthritis. The intent of this experiment is to create an ibuprofen matrix tablet including xanthan gum, gelatin, and pectin **[11]**.

MATERIALS AND METHODS

Materials

Ibuprofen was received form Solara Active pharma as gift sample. The excipients were received from Ashland, an excipient trading company.

Technique for preparing sustained release tablets:

It has been recognized that the current method is frequently employed in the creation of tablets exhibiting sustained release.

Direct Compression: It is the most ubiquitous and economical methodology. It is the most modest and intuitive approach **[12]**. This method is employed in the creation of the sustained release tablet due to the utilization of several effective excipients, The mixture is then sieved through mesh number ASTM 40, prior merging more than once to generate granules that are ready for compression **[13]**.

(a) (b) (c) (d)

Figure 1: a) Compression machine, b) Gelatin gum based tablet, c) Xanthan gum based tablet, d) Pectin gum based tablet

Preparation of SR matrix tablets:

The medicated polymer ratios of 1:0.1, 1: 0.25, 1:0.5, 1:075 and 1.1 for pectin, xanthan gum and gelatin gum were employed to make Ibuprofen SR matrix tablets. Magnesium stearate was incorporated as lubricant, lactose was utilized as a diluent, and GG, PG, and XG were utilized as

matrix-forming components. Each item was weighed, mixed, then put through a 40 sieve. Using 12 mm flat-faced punches, a direct compression approach was used to compress the lubricated formulations **[14]**.

Table 1: Formulation of Pectin Gum (PG), Gelatin Gum (GG) & Xanthan Gum (XG) matrix tablet

	Quantity in mg														
Ingredients	**P1**	**P2**	**P3**	**P4**	**P5**	**G1**	**G2**	**G3**	**G4**	**G5**	**X1**	**X2**	**X3**	**X4**	**X5**
Ibuprofen	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**	**800**
Pectin	**80**	**200**	**400**	**600**	**800**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Gelatin	**-**	**-**	**-**	**-**	**-**	**80**	**200**	**400**	**600**	**800**	**-**	**-**	**-**	**-**	**-**
Xanthan gum	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**80**	**200**	**400**	**600**	**800**
Magnesium stearate	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**
Lactose	**3350**	**3230**	**3020**	**2820**	**2620**	**3350**	**3230**	**3020**	**2820**	**2620**	**3350**	**3230**	**3020**	**2820**	**2620**

Evaluation of Fabricated Matrix Tablets: The In-process methodology was implemented to assess the weight homogeneity of all manufactured matrix tablets. The Roche friabilator was used to determine friability. A Pfizer hardness tester was used to measure hardness. A Vernier caliper was employed to measure thickness **[15, 16]**.

Tablet Hardness: A Pfizer hardness tester was used to ascertain the tablets' hardness. Five pills were examined after being chosen at random. It was calculated to find the percentage variance **[7]**.

Tablet Thickness: A Vernier caliper was calibrated to measure the thickness for each of five tablets. By encased in the tablet between the Vernier calipers' two arms, the thickness was measured. The data gathered were tabulated after the percentage deviation was computed **[18, 19]**.

Uniformity of Weight: Twenty pills were weighed individually and collectively in order to perform the weight variation test. The average weight was then determined, followed by the percentage deviation and weight variation.

Friability Test: We assessed the tablets' friability as per recommended procedure of European Pharmacopoeia (1997), by utilizing the Roche friability apparatus with the drum whirling at 25 rpm for four minutes **[20, 21]**. A weight loss computation was accomplished using the twenty pills that were weighed both before and after the assessment (n = 1). After computing the percentage variation, the friability test was carried out. Using the following formula, the % friability of each batch was determined:

Percentage friability = (Initial weight - Final weight/Initial weight) × 100

In-vitro drug release study:

Using a USP I apparatus, in vitro drug release was investigated for two hours using 900 ml of a dissolving media kept at 37±1°C with 0.1 N HCl (pH 1.2) and four hours

using pH 7.2 phosphate buffer. Every hour, 5 millilitres of the sample were removed and replaced with an equivalent volume of freshly prepared dissolving medium with the same p^H. Collected samples were analyzed spectrophotometrically at 264 nm, and cumulative percent drug release was calculated. The investigation was carried out three times **[22]**.

Table 2: Evaluation parameters for Pectin based pills

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm2)	Cumulative % Drug Release
P1	**0.306**	**3.4**	**6.8**	**70.0**
P2	**0.299**	**3.2**	**6.2**	**70.2**
P3	**0.310**	**3.4**	**8.2**	**82.2**
P4	**0.269**	**3.1**	**7.9**	**67.3**
P5	**0.287**	**3.5**	**5.8**	**59.3**

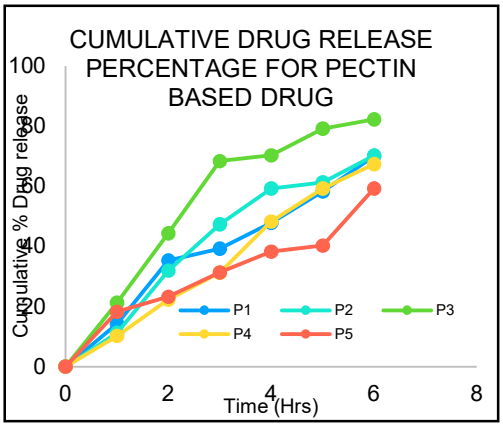

Figure 2: Dissolution graph of Ibuprofen Pectin based Tablet

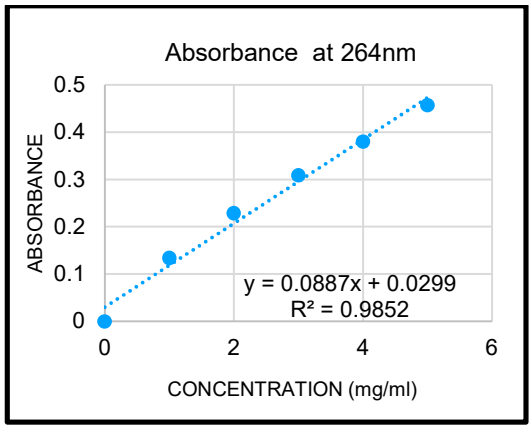

Figure 3: Linearity graph of Ibuprofen Pectin based Tablet

Table 3: Cumulative Drug Release Percentage of Pectin Based Ibuprofen Tablets

TIME (hrs)	Cumulative Drug Release percentage for Pectin based Ibuprofen Sustained release Tablet				
	P1	P2	P3	P4	P5
0	**0**	**0**	**0**	**0**	**0**
1	**14.3**	**11.3**	**21.3**	**10.3**	**18.3**
2	**35.3**	**32.0**	**44.4**	**22.3**	**23.3**
3	**39.3**	**47.4**	**68.4**	**31.3**	**31.3**
4	**47.8**	**59.2**	**70.2**	**48.3**	**38.3**
5	**58.3**	**61.2**	**79.1**	**59.3**	**40.3**
6	**70.0**	**70.2**	**82.2**	**67.3**	**59.3**

Table 4: Evaluation parameters for Xanthan Gum based Tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm2)	Cumulative % Drug Release
X1	**0.306**	**3.3**	**5.8**	**90.7**
X2	**0.301**	**3.5**	**6.7**	**98.8**
X3	**0.299**	**3.0**	**5.2**	**99.5**
X4	**0.298**	**3.4**	**4.9**	**100.3**
X1	**0.306**	**3.3**	**5.8**	**90.7**

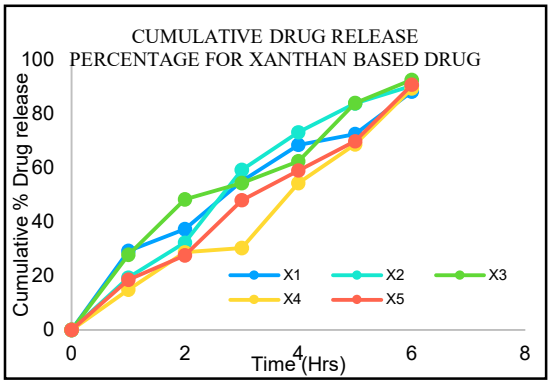

Figure 4: Dissolution graph of Ibuprofen Xanthan based Tablet

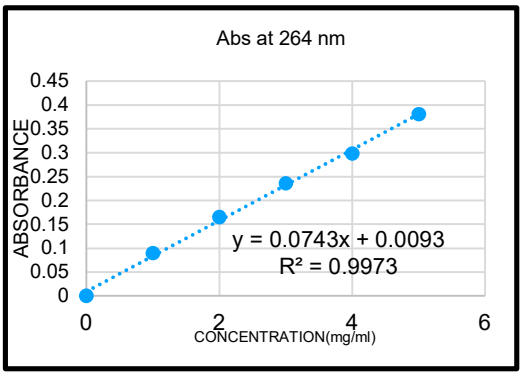

Figure 5: Linearity graph of Ibuprofen Xanthan based Tablet

Table 5: Cumulative Drug Release Percentage of Xanthan Based Ibuprofen Tablets

TIME (hrs)	Cumulative Drug Release percentage for Xanthan based Ibuprofen Sustained release Tablet				
	X1	X2	X3	X4	X5
0	0	0	0	0	0
1	29.2	19.3	27.8	14.9	18.5
2	37.2	32.2	48.3	28.7	27.6
3	55.0	59.1	54.2	30.3	48.0
4	68.4	73.1	62.4	54.3	59.0
5	72.4	83.7	83.8	68.6	69.8
6	88.1	90.3	92.5	89.3	90.7

Table 6: Evaluation parameters for Gelatin Gum based Tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm2)	Cumulative % Drug Release
G1	0.276	3	4.1	88.1
G2	0.284	3.4	4.9	90.3
G3	0.306	3.1	4.2	92.5
G4	0.291	3.2	4.0	89.3
G5	0.246	3	4.6	90.7

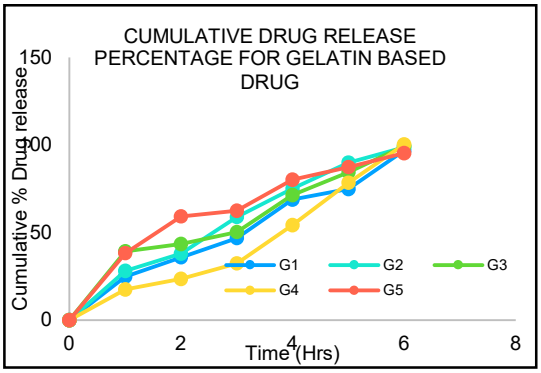

Figure 6: Dissolution graph of Ibuprofen Xanthan based Tablet

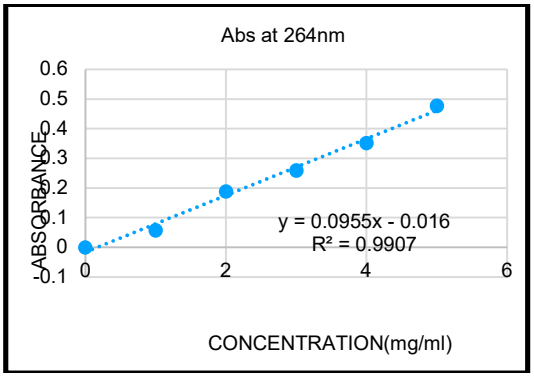

Figure 7: Linearity graph of Ibuprofen Xanthan based Tablet

Table 7: Cumulative Drug Release Percentage of Gelatin Gum Based Ibuprofen Tablets

TIME (hrs)	Cumulative Drug Release percentage for Gelatin based Ibuprofen Sustained release Tablet				
	G1	G2	G3	G4	G5
0	0	0	0	0	0
1	24.9	28.1	39.3	17.5	38.4
2	35.9	38.0	43.5	23.5	59.3
3	46.9	59.0	50.4	32.5	62.5
4	68.9	75.0	71.4	54.3	80.2
5	74.9	90.0	84.6	78.5	87.4
6	96.9	98.8	99.5	100.3	95.4

RESULT AND DISCUSSION:

The pharmacopoeia's prerequisites for congruence of weight were accomplished by the designed matrix tablets. According to Indian Pharmacopoeia, every tablet met the assay specifications. According to the table, its thickness, hardness, and percentile friability were all within acceptable bounds. Every tablet met the assay requirements, demonstrating their reliable quality. The resilience and stability of the tablet formulations were demonstrated by the physical criteria, which included thickness, hardness, and friability, all being within acceptable bounds. These results confirm that the formulation design and manufacturing procedure are appropriate for creating high-quality matrix tablets.

CONCLUSION:

In summary, the investigation showed that the examined gums' sustained release performance varied greatly, with gelatin showing the greatest effectiveness and Xanthan gum and pectin following closely behind. These results imply that while xanthan gum and pectin might be appropriate for compositions requiring a moderate release profile, gelatin is the most effective gum for applications needing prolonged release. In food and medicinal formulations, the differential performance emphasises how crucial it is to choose the right gum based on the intended release characteristics. Gelatin, Xanthan gum, and Pectin were shown to have the highest overall sustained release performance among the gums that were used.

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