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FORMULATION DEVELOPMENT AND EVALUATION OF POLYHERBAL IMMEDIATE RELEASE TABLETS FOR ANTIUROLITHIATIC ACTIVITY

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ABSTRACT:

The present study focuses on the development and evaluation of polyherbal immediate release tablets for antiurolithiatic activity, aimed at providing rapid therapeutic action in the management of kidney stone disease. Urolithiasis is a common and recurrent disorder characterized by the formation of crystalline stones in the urinary tract, requiring prompt and effective treatment. In this research, a combination of medicinal herbs including Pashanbheda, Gokshura, Kulthi, Nagarmotha, Varuna, Manjistha, and Hajarulayahuda Bhasma was utilized due to their well-known antiurolithiatic and nephroprotective properties. The tablets were prepared using the direct compression method with the incorporation of superdisintegrants such as croscarmellose sodium and crospovidone to enhance rapid disintegration and drug release. Preformulation studies confirmed acceptable flow and compressibility characteristics of the powder blend, making it suitable for tablet formulation. A total of six formulations (F1–F6) were developed and evaluated for various pre- and post-compression parameters including angle of repose, bulk density, hardness, friability, weight variation, disintegration time, and wetting time. All formulations complied with pharmacopeial standards, showing satisfactory mechanical strength and rapid disintegration. In vitro dissolution studies demonstrated significant drug release within a short duration, with formulation F3 exhibiting the highest release of approximately 99.33% within 25 minutes. The results indicate that the developed polyherbal immediate release tablets are effective in providing rapid drug release and hold promising potential for the treatment of urolithiasis.

INTRODUCTION:

Immediate release drug delivery systems (IRDDS) are designed to facilitate rapid disintegration and dissolution of the active pharmaceutical ingredient, resulting in a prompt onset of therapeutic action. These systems are particularly advantageous in clinical conditions requiring immediate relief and for patient populations such as paediatric, geriatric, and dysphagic individuals who experience difficulty in swallowing conventional solid dosage forms. The absence of rate-controlling barriers in immediate release formulations allows the drug to be released quickly upon administration, thereby enhancing bioavailability and therapeutic efficiency [1,2].

Oral drug delivery remains the most widely preferred route due to its convenience, cost-effectiveness, and high patient compliance. However, conventional tablets and capsules often exhibit delayed drug release and may not be suitable in acute conditions where rapid pharmacological response is essential. Immediate release tablets overcome these limitations by ensuring fast disintegration in the gastrointestinal environment, followed by rapid dissolution and absorption. The performance of such systems is governed by factors including drug solubility, particle size, and the selection of appropriate excipients, particularly superdisintegrants such as croscarmellose sodium and crosspovidone, which facilitate tablet breakup through mechanisms like swelling and wicking [2].

Urolithiasis (kidney stone disease) is a prevalent and recurrent urological disorder characterized by the formation of crystalline aggregates in the urinary tract due to supersaturation of urinary solutes. The disease affects a significant proportion of the global population, with higher incidence reported in individuals aged 30–50 years. The pathogenesis of urolithiasis involves a complex sequence of events including nucleation, crystal growth, aggregation, and retention within the renal system. Calcium oxalate stones are the most commonly encountered type, followed by uric acid, struvite, and cystine calculi [3,4].

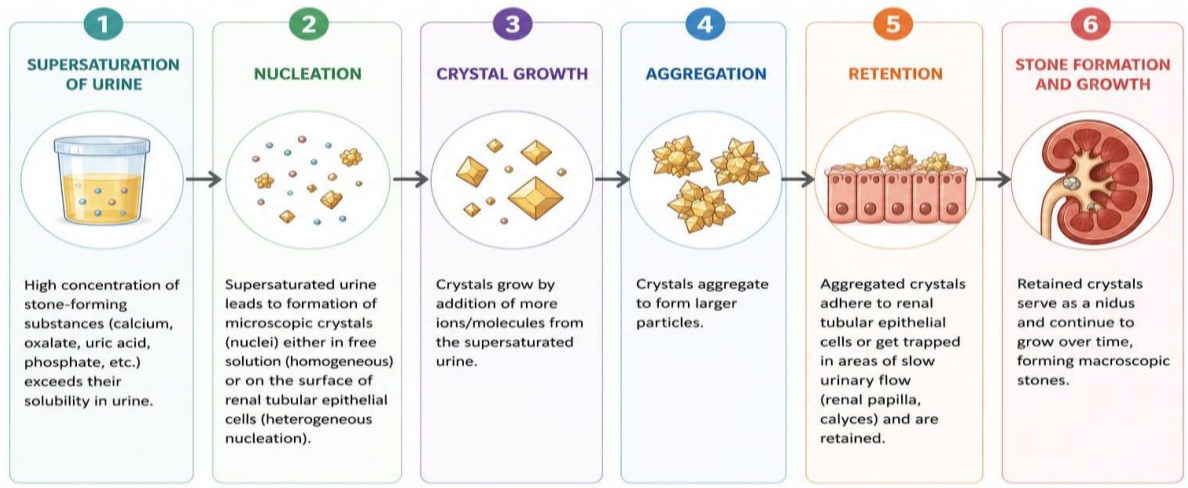

Fig 1: Pathophysiology of Urolithiasis.

Clinically, urolithiasis presents with severe flank pain (renal colic), haematuria, nausea, and urinary tract obstruction, significantly affecting patient quality of life. Current management strategies depend on the size and composition of the stones and include pharmacological interventions such as non-steroidal anti-inflammatory drugs and alpha-blockers, as well as surgical procedures including extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS), and percutaneous nephrolithotomy (PCNL). Despite these advancements, recurrence rates remain high, necessitating the development of safer and more effective therapeutic approaches.

In recent years, polyherbal formulations have gained considerable attention due to their synergistic therapeutic effects, reduced side effects, and long-standing use in traditional medicine for the management of urinary disorders. Herbs such as Pashanbheda, Goksharu, Kulthi, Varuna, and Manjistha are well documented for their antiurolithiatic, diuretic, and nephroprotective properties [5].

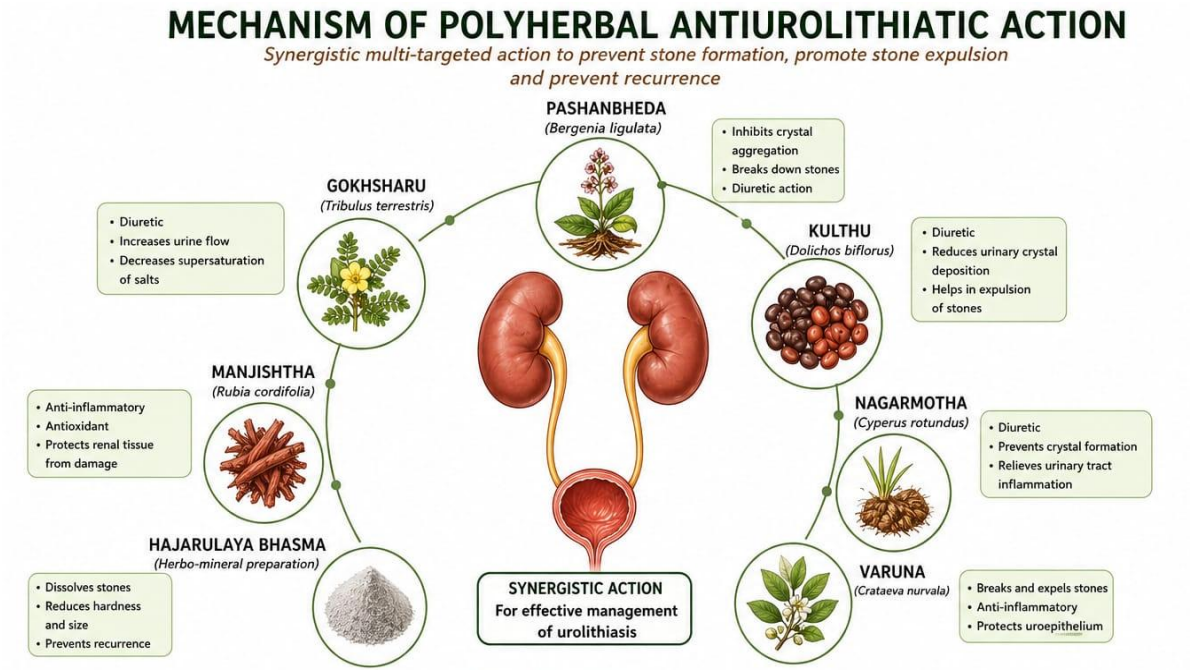

Fig 2:Mechanism of Polyherbal Antiurolithiatic Action.

The integration of polyherbal therapy with immediate release drug delivery systems offers a promising strategy for the rapid management of urolithiasis. Immediate release tablets can ensure quick onset of action, improved patient compliance, and enhanced therapeutic outcomes, particularly in acute episodes of renal colic.
However, limited research has been reported on the development of polyherbal immediate release formulations specifically targeting urolithiasis with optimized disintegration and drug release characteristics. Therefore, the present study aims to formulate and evaluate polyherbal immediate release tablets using different superdisintegrants and to assess their potential for rapid therapeutic action in the management of kidney stone disease [6].

MATERIALS:

Polyherbal immediate-release tablets were formulated using a combination of medicinal plants recognized for their antiurolithiatic properties. The selected herbal ingredients included Pashanbheda (Bergenia ligulata), Gokshura (Tribulus terrestris), Kulthi (Macrotyloma uniflorum), Nagarmotha (Cyperus rotundus), Varuna (Crataeva nurvala), Manjistha (Rubia cordifolia), and Hajarulayahuda (Bhasma form). These materials were procured from an authenticated herbal supplier and verified for their botanical identity.
Excipients incorporated in the formulation comprised microcrystalline cellulose (MCC) as a diluent, sucrose as a palatability enhancer, croscarmellose sodium (2%) and crospovidone as superdisintegrants, starch paste as a binder, and magnesium stearate as a lubricant. All ingredients used were of pharmaceutical grade and utilized without further purification [7].

PREFORMULATION STUDY:

Formulation of Immediate release herbal tablets of kidney stone**:**
Preformulation studies were carried out to evaluate the physicochemical properties of the polyherbal powder blend prior to tablet compression. The herbal ingredients, namely Pashanbheda, Goksharu, Kulthi, Nagarmotha, Varuna, Manjistha, and Hajarulayahuda Bhasma, were evaluated for organoleptic characteristics such as colour, odour, and appearance. The powder blend was sieved to obtain uniform particle size distribution suitable for granulation.

Flow properties of the blend were assessed by determining angle of repose, bulk density, and tapped density. Compressibility characteristics were evaluated using Carr's index and Hausner's ratio. These parameters are essential to predict flowability, compressibility, and stability of the formulation during tablet manufacturing.
The results of preformulation studies indicated that the polyherbal powder blend exhibited acceptable physicochemical properties. However, due to the inherent poor flowability and compressibility of herbal powders, the direct compression method was selected to ensure uniform tablet compression.

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Method of Formulation Of Polyherbal Antiurolithiatic Tablets (Direct Compression)
Polyherbal immediate release tablets were prepared by the direct compression technique following systematic blending and lubrication steps [8].

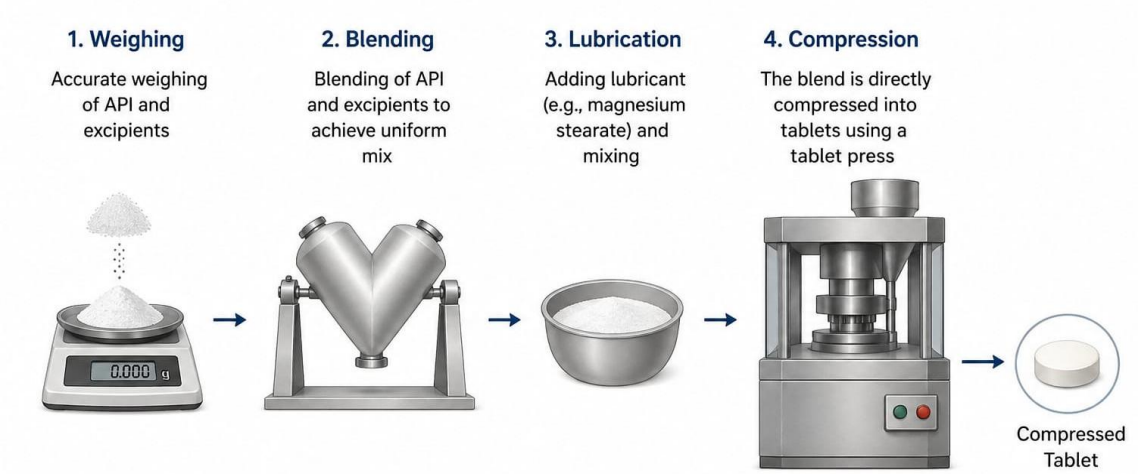
All herbal ingredients (*Pashanbheda*, *Goksharu*, *Kulthi*, *Nagarmotha*, *Varuna*, *Manjistha*, and *Hajarulayahuda Bhasma*) and excipients were individually passed through a #60 mesh sieve to ensure uniform particle size distribution [9]. The accurately weighed quantities of herbal powders were geometrically blended in a mortar to achieve homogeneity [10].

Microcrystalline cellulose (MCC) and sucrose were incorporated as diluent and taste-masking agent, respectively, and mixed thoroughly with the herbal blend. The selected superdisintegrant (either crosscarmellose sodium or crospovidone, depending on formulation batch F1–F6) was then added and blended uniformly [11].
Magnesium stearate was finally introduced as a lubricant and mixed gently for a short duration (2–3 minutes) to avoid over-lubrication, which may adversely affect tablet hardness and dissolution [12].

Table 1: Formulation Composition of Polyherbal Antiurolithiatic Tablets

INGREDIENT	F1	F2	F3	F4	F5	F6
Pashanbheda	46.87	46.87	46.87	46.87	46.87	46.87
Goksharu	31.2	31.2	31.2	31.2	31.2	31.2
Kulthi	24.5	24.5	24.5	24.5	24.5	24.5
Nagarmotha	15	15	15	15	15	15
Varuna	12.5	12.5	12.5	12.5	12.5	12.5
Manjistha	15	15	15	15	15	15
H. Bhasma	16.25	16.25	16.25	16.25	16.25	16.25
MCC	48.68	44.93	41.18	48.68	44.93	41.18
Sucrose	10	10	10	10	10	10
Magnesium stearate	10	10	10	10	10	10
Cross carmellose sodium	5	8.75	12.5	-	-	-
Cross povidone	-	-	-	5	8.75	12.5
Povidone	15	15	15	15	15	15
Total	250 mg	250 mg	250 mg	250 mg	250 mg	250 mg

The final powder blend was evaluated for flow properties and directly compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches [8]. Compression force was optimized to obtain tablets with adequate mechanical strength without compromising disintegration performance [13].



Fig,3: Direct Compression Method.

PRE-COMPRESSION PARAMETERS:
Angle of Repose (θ):
Purpose: Measures flowability of powder.
Formula: $\theta = \tan^{-1} \frac{h}{r}$

Bulk Density (Db):
Purpose: Volume occupied by powder before tapping.
Formula: $\frac{Mass\ of\ material}{Total\ volume\ of\ material}$
Where: M = mass of powder
Vb = bulk volume
Tapped Density (Dt):
Purpose: Density after mechanical tapping.
Formula: $\frac{Mass}{Tapped\ volume}$
Where: Vt = tapped volume
Carr's Compressibility Index (%):
Purpose: Indicates compressibility and flow.
Formula: $\frac{Tapped\ density - Bulk\ density}{Tapped\ density} \times 100$
Hausner's Ratio:
Purpose: Measures interparticle friction.
Formula: $\frac{Tapped\ density}{Bulk\ density}$

POST COMPRESSION:
General appearance- of polyherbal immediate-release tablets is evaluated by visually inspecting the tablets for color, shape, size, surface texture, and the presence of any defects such as cracks, capping, or mottling. This test ensures uniformity and acceptability of the formulation. In polyherbal tablets, slight variation in color or odor may occur due to the natural origin of plant extracts.

Weight variation test- is performed by weighing 20 tablets individually and calculating the average weight, after which individual weights are compared with the average. According to standards such as the Indian Pharmacopoeia, the permissible limit for tablets weighing more than 250 mg is ±5%. This test ensures uniform distribution of the herbal ingredients in each tablet.
100% weight Variation = (IW-AW)
Where, IW= Individual weight
AW= Average Weight

Thickness and diameter- are measured using a vernier caliper to ensure uniformity in tablet size, which is important for packaging, handling, and maintaining consistent dosing. Variations in thickness can indicate issues during compression.

Hardness test- determines the mechanical strength of the tablet using instruments like Monsanto or Pfizer hardness testers. For immediate-release tablets, a hardness range of 3–6 kg/cm² is generally acceptable. Adequate hardness ensures the tablet can withstand handling while still disintegrating properly.

Friability test- is carried out using a Roche Friabilator, where tablets are subjected to mechanical shock by rotating at 25 rpm for 100 revolutions. A weight loss of not more than 1% is considered acceptable. This test evaluates the tablet's ability to resist abrasion during packaging and transportation.
Friability= (W1-W2)/W1×100
Where, W1= Initial Weight
W2=Final Weight

Disintegration test- measures the time required for tablets to break down into smaller particles in a specified medium, usually water or simulated gastric fluid, at 37°C. As per the Indian Pharmacopoeia, immediate-release tablets should disintegrate within 15 minutes. This ensures rapid availability of the active constituents.

Wetting time- is an important parameter especially for immediate-release tablets, indicating how quickly the tablet absorbs water and begins to disintegrate. It is determined by placing a tablet on a wetted tissue paper in a petri dish containing water and recording the time taken for complete wetting. A shorter wetting time indicates faster disintegration and improved dissolution, which is desirable for immediate-release formulations.

RESULT:

In the present study, polyherbal immediate release antiurolithiatic tablets were successfully formulated using the direct compression method. Herbal ingredients commonly used for antiurolithiatic activity such as Gokshura, Punarnava, and Pashanbhed were incorporated.

Superdisintegrants like crospovidone and croscarmellose sodium were used to achieve rapid drug release. Mannitol was used as a diluent to enhance mouthfeel.
A total of six formulations (F1–F6) were prepared. The powder blends showed good flow properties with: Angle of repose < 30°, Carr's index < 25%, Hausner's ratio < 1.35. This indicates good compressibility and suitability for direct compression. All tablets showed Uniform weight variation within IP limits, Adequate hardness (2–5 kg/cm²), Friability < 1% (good mechanical strength)

Pre-Formulation Parameters:
Preformulation studies were carried out to evaluate the physicochemical and flow properties of the polyherbal powder blend before compression. These studies are essential to ensure the development of a stable, uniform, and effective dosage form. Parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were determined to assess of the powder blend.
Carr's index = [(Tapped density – Bulk density) / Bulk density] × 100
Hausner's Ratio
Hausner's ratio was used to assess interparticle friction and flowability of the powder.
Hausner's ratio = Tapped density / Bulk density
A value less than 1.25 indicates good flow properties, whereas higher values indicate poor flow. flowability and compressibility**.**

Angle of Repose:
The angle of repose was determined using the fixed funnel method. The powder blend was allowed to flow through a funnel to form a conical heap. The height (h) and radius (r) of the heap were measured, and the angle of repose (θ) was calculated using the following equation:
$\theta = \tan^{-1}(h/r)$
Where: θ = Angle of repose
h = Height of the powder heap
r = Radius of the base
Pre-compression parameters were evaluated for all formulation (f1-f6) to determine flow properties and compressibility behaviours of powder blends.

Bulk Density:
Bulk density was determined by introducing a known mass of powder into a graduated cylinder and measuring its bulk volume.
Bulk density = Mass of powder / Bulk volume of powder

Tapped Density
Tapped density was measured by mechanically tapping the cylinder containing the powder until a constant volume was obtained.
Tapped density = Mass of powder / Tapped volume of powder

Carr's Index
Carr's index was calculated to evaluate the compressibility of the powder blend. Carr's index = [(Tapped density – Bulk density) / Bulk density] × 100

Hausner's Ratio
Hausner's ratio was used to assess interparticle friction and flowability of the powder.
Hausner's ratio = Tapped density / Bulk density
A value less than 1.25 indicates good flow properties, whereas higher values indicate poor flow.

Table 2: Pre—compression parameters

PARAMETERS	F1	F2	F3	F4	F5	F6
Bulk density	0.45	0.50	0.50	0.59	0.48	0.48
tapped density	0.73	0.75	0.62	0.75	0.66	0.72
Hausner's ratio	1.62	1.50	1.25	1.20	1.36	1.50
Carr's index (%)	38.35	33.37	20.09	33.80	26.67	33.33
Angle of repose	42.92	34.99	36.30	34.91	0.69	34.50
Flow type	Good	Good	Fair	Poor	Poor	Good

Post compression parameters:

The post-compression evaluation of polyherbal antiurolithiatic tablets showed no significant variation in tablet weight, indicating uniform die filling. The thickness of all formulations was found in the range of 1–1.8 mm. The hardness ranged between 2–5 kg/cm², ensuring adequate mechanical strength.

All formulations passed pharmacopeial limits for friability (<1%) and weight variation. The in vitro disintegration time was found within acceptable limits, confirming suitability for immediate release tablets**.**

Table 3: Post-compression parameters of polyherbal antiurolithiatic tablets

Parameters	F1	F2	F3	F4	F5	F6
Hardness (kg/cm^2)	2	2	2	2	2	2
Thickness	1.8	1.8	1.8	1.8	1.8	1.8
Friability	0.3	0.2	0.2	0.2	0.5	0.4
Dissolution time	8.30	6.10	5.10	7.40	4	4.30
Wetting time (sec)	45	41	36	46	42	37
Weight variation	(247-250mg) within IP limits ±0.5%					

In Vitro Disintegration Study

The disintegration test was performed to evaluate the time required for immediate release polyherbal tablets to break down under standard conditions. The study was carried out according to pharmacopoeial standards.

Table 4: In vitro disintegration data

Batch Code	Disintegration Time (min)	Limit	Result
F1	10.5	≤ 15 min	Pass
F2	9.1	≤ 15 min	Pass
F3	7.2	≤ 15 min	Pass
F4	6.5	≤ 15 min	Pass
F5	5.4	≤ 15 min	Pass
F6	5.9	≤ 15 min	Pass

All batches complied with the pharmacopoeial limit for disintegration time (not more than 15 minutes). Among all formulations, batch F3 showed the fastest disintegration time of 34 seconds, indicating efficient tablet breakdown and rapid drug release. This may be attributed to the optimal concentration of super disintegrant. Other batches showed comparatively slower disintegration.

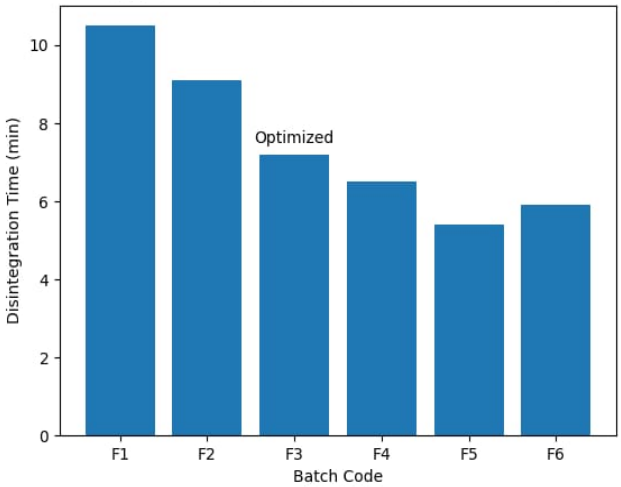


Fig. 5: In vitro disintegration profile

In Vitro Dissolution Study

The in vitro dissolution study of polyherbal immediate release antiurolithiatic tablets was carried out using USP Type II (paddle) dissolution apparatus.
Method:
Dissolution medium: 900 ml phosphate buffer (pH 6.8)
Temperature: 37 ± 0.5°C
Rotation speed: 50 rpm
Sampling interval: 5, 10, 15, 20, 25 minutes
withdrawn: 5 ml, replaced with fresh medium

Table 5: In vitro drug release data

Time (min)	F1(%)	F2(%)	F3(%)	F4(%)	F5(%)	F6(%)
0	0	0	0	0	0	0
5	10	12	15	8	11	13
10	25	28	35	20	27	30
15	50	55	65	45	52	56
20	70	75	85	65	72	78
25	93.19	95.24	99.33	90.56	93.44	96.05

The dissolution profile indicates that all formulations exhibited rapid drug release, confirming their immediate release nature. Among all, formulation F3 showed the highest drug release (≈99.33%) within 25 minutes, indicating superior performance.
The faster drug release in F3 may be attributed to the higher efficiency of superdisintegrant, which enhances tablet breakup and dissolution rate.

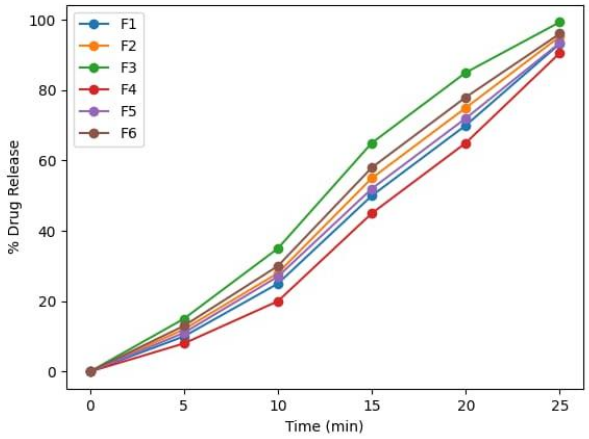


Fig. 4:In vitro dissolution profile

CONCLUSION:
The present study successfully developed and evaluated polyherbal immediate release tablets for antiurolithiatic activity using the direct compression method. All formulations (F1–F6) exhibited acceptable preformulation and post-compression parameters, confirming good flow properties, compressibility, mechanical strength, and compliance with pharmacopeial standards.

Among all the formulations, batch F3 was identified as the optimized formulation, owing to its superior performance in critical quality attributes. Batch F3 showed excellent drug release of 99.33% within 25 minutes, indicating rapid and efficient dissolution. Furthermore, the disintegration time of batch F3 was found to be approximately 5.10 minutes, which is well within the acceptable limit for immediate release tablets, ensuring quick breakdown and faster onset of therapeutic action.

The enhanced performance of batch F3 can be attributed to the optimal concentration of super disintegrant, which significantly improved tablet disintegration, wetting time, and dissolution rate. These findings demonstrate that the developed formulation is capable of providing rapid drug release, making it highly suitable for the effective management of urolithiasis, especially in acute conditions requiring immediate relief.

In conclusion, the optimized polyherbal formulation (F3) represents a promising, safe, and effective immediate release dosage form. However, further in vivo and clinical studies are recommended to confirm its therapeutic efficacy and long-term safety.

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