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FORMULATION AND EVALUATION OF A NOVEL POLYHERBAL ORAL MEDICATED JELLY FOR TREATMENT OF UROLITHIASIS

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Keywords:

Lithotriptic activity, Oral medicated jelly, Polyherbal formulation, Urolithiasis

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ABSTRACT: Background: Urolithiasis is a disease of the genitourinary system, characterised by occurrence of urinary stones and affecting approximately 12% of the global population. It is also linked to chronic diseases like chronic renal disease, cardiovascular disease thereby posing significant health risks. Contemporary treatments are symptomatic and fail to produce lithotriptic activity and thus recurrence is common. This study involves development of polyherbal formulation and evaluation of its lithotriptic activity. **Methodology:** Hydroalcoholic (HA) extracts of *Tribulus terrestris, Cynodon dactylon, and Kalanchoe pinnata* were formulated into a polyherbal oral medicated jelly (OMJ). The OMJ was evaluated for characteristics like hardness, cohesion, springiness, gumminess, and chewiness using a texture analyser. The lithotriptic activity was evaluated using HPLC analysis. Calcium oxalate crystals were incubated with HA extracts in egg membrane for 72 hours. The residual contents were then analysed using HPLC. Cystone was used as a standard. **Results:** Texture analysis of OMJ revealed the characteristics such as: gumminess (431g), springiness (36.70), hardness (518g), cohesiveness (0.83), and chewiness (155 mJ) at pH of 4.3. The dissolution of calcium oxalate in presence of OMJ was found to be 73.9%, whereas dissolution of 92.5% was observed with Cystone. **Conclusion:** The OMJ was developed and its *in-vitro* lithotriptic effect was evaluated which demonstrated the potential therapeutic efficacy of OMJ in dissolving calcium oxalate crystals thereby envisaging the role of OMJ in management of urolithiasis. Further preclinical investigations are needed to validate its therapeutic efficacy and safety.

INTRODUCTION: Urolithiasis is a renal complication associated with occurrence of stones across the urinary tract [1]. Commonly four types of kidney stones have been identified namely: calcium oxalate, uric acid, struvite, and cystine [2]. Predominantly occurring are Calcium Oxalate Stones, resulting from the crystallisation of calcium ions and oxalate molecules within the urinary tract. Calcium containing stones may exist in the form of pure calcium oxalate (50%) or calcium phosphate (5%) or a mixture of both (45%) [1, 2, 3, 9]. Urolithiasis is a global health concern predicted to affect 1 in 10 people of a population by 2045 it primarily affects populations in the age of 20 to 45 years, affecting 11% men and 8% women worldwide [2].

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Urinary stones are the result of different mechanisms (low urine pH, hyperuricosuria, hyperoxaluria, high urinary calcium, low urine volume [3, 4]. Exceeding the supersaturation limit of the stone precursor in urine is the most widely accepted mechanism [3]. Kidney stones formation occurs through four steps: crystal nucleation, crystal growth, crystal aggregation and crystal retention [5]. Any crystal retained in the nephron can become a stone because it is a nidus of further

crystal growth and deposition of other ionic species. The retention and growth of these crystals leads to the formation of insoluble stones. Hydration is the first step in medical management by increasing fluid intake sufficiently to produce 2–3 L/day of urine. Corticosteroids, phosphor-diesterase type 5 (PDE-5) inhibitors, calcium-channel blockers, and α-adrenergic blockers have been evaluated as part of the medical expulsive therapy [6, 7, 8]. Thiazide and other thiazide type diuretics have shown promising results in the treatment of urolithiasis. Citrate can inhibit kidney stone formation through a variety of mechanisms. It reduces the urinary supersaturation of calcium salts by forming soluble complexes with calcium ions and by inhibiting the crystal growth and aggregation. Extracorporeal shockwave lithotripsy (ESWL) is indicated preferentially in renal stones up to 2 cm in diameter [8, 9, 10]. Despite the availability of conventional treatments, urolithiasis remains a recurrent condition due to the lack of agents with true lithotriptic activity. Existing therapies primarily offer symptomatic relief without effectively dissolving existing stones. This highlights the need for safer, more effective alternatives. The present study aims to develop and evaluate a polyherbal oral medicated jelly combining traditionally used anti-urolithiatic herbs to explore its potential in dissolving calcium oxalate stones and offer a novel approach for the management of urolithiasis.

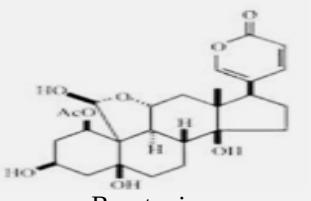
TABLE 1: TRADITIONAL NAMES AND CLASSIFICATION OF HERBAL DRUGS USED

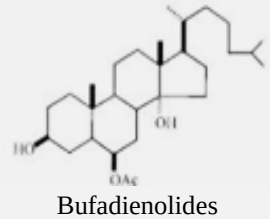
Plant/herb	**Bryophyllum** [11, 12, 13]	**Gokhru** [14, 15]	**Durva** [16, 17, 18, 19]
Scientific names	*Kalanchoe pinnata* (KP)	*Tribulus terrestris* (TT)	*Cynodon dactylon* (CD)
Taxonomic classification			
Kingdom	*Plantae*	*Plantae*	*Plantae*
Phylum	*Tracheophyta*	*Tracheophyta*	*Streptophyta*
Class	*Magnoliopsida*	*Dicotyledonae*	*Equisetopsida*
Order	*Saxifragales*	*Geraniales*	*Poales*
Family	*Crassulaceae*	*Zygophyllaceae*	*Poaceae*
Genus	*Kalanchoe*	*Tribulus*	*Cynodon*
Species	*Kalanchoe pinnata*	*Tribulus terrestris*	*Cynodon dactylon*

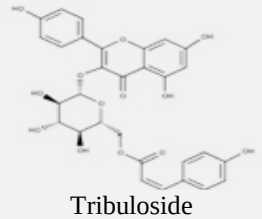
TABLE 2: TRADITIONAL USE AND PHYTOCHEMICALS PRESENT IN HERBS USED

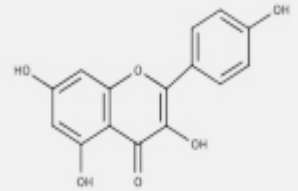
Herb	***Kalanchoe pinnata*** [11, 12, 13]	***Tribulus terrestris*** [14, 15]	***Cynodon dactylon*** [17, 18, 19]
	Leaves	**Fruit**	**Leaves**
Traditional uses	Antilithiatic, diuretic, nephroprotective.	Diuretic, lithotriptic, urinary disinfectant	Diuretic
Phytoconstituents	Polyphenols: Bufadienolides (bryotoxin A, B, C) astragalin, luteolin, rutin, kaempferol, quercetin.	Kaempferol, kaempferol-3-glucoside, kaempferol-3-rutinoside, tribuloside, terrestrinin A, B, D, J-T, K.	4H-pyran-4-one, 2,3-dihydro-3,5-dihydroxy-6-methyl, thymol, 1,2-cyclopentanediol, 3-methyl

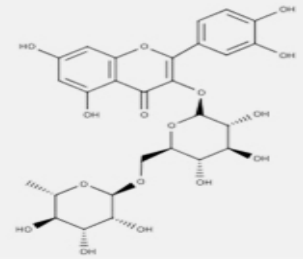
TABLE 3: STRUCTURES OF THE MAJOR PHYTOCONSTITUENTS USED

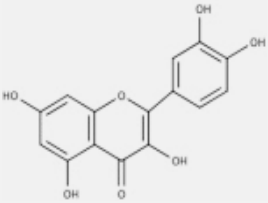

Bryotoxin


Bufadienolides


Tribuloside


Kaempferol


Rutin


Quercetin

MATERIALS: Cystone tablets were procured from Himalaya Drug Company (India) and served as the reference formulation to evaluate anti-urolithiatic activity. calcium oxalate (analytical grade) was used as a lithogenic agent. Phosphate buffer (IP grade) was prepared as per standard protocols and used to maintain the required pH during in vitro studies. Hydrochloric acid (HCl) and ammonia solution (NH_4OH) were used for decalcification of the egg membrane. Carrageenan was utilized as a gelling agent in the simulated formulation matrix. Sugar and sodium benzoate were incorporated as excipients in the preparation of syrup-based formulations. Agress 1100 HPLC system were used for HPLC analysis. CT3 Texture Analyzer (Brookfield Laboratories, Middleboro, USA) was used for texture analysis. 0.1Mv Lcd lab India pico digital pH meter was employed for pH measurement.

Methodology:

Extraction: Powdered *Tribulus terrestris* and crushed leaves of *kalanchoe pinnata and cynodon dactylon* were separately stored in airtight containers. The hydroalcoholic extract of each plant material was prepared by macerating the powdered plant parts in distilled water and 95% ethanol, and maintained in an incubator at 37°C for 24 h. Then, the samples were sonicated using an ultrasound sonicator (25-42 kHz waves) for one hour followed by maceration for 24 h. The herbal extracts were then filtered through Whatman filter paper using vacuum suction. The filtrate was then concentrated in an electric water bath to obtain the herbal extracts.

Formulation Development: Medicated jellies were prepared by using Carrageenan as a gelling agent in different concentrations as given in the formula **Table 4**. The gelling agents were tried initially at various concentrations to achieve desired appearance, stiffness and release. Citric acid is used to maintain the pH. Sodium benzoate is used as a preservative and sugar is used as sweetening and bulking agents.

The jellies are prepared by taking carrageenan, citric acid in beaked and heated with continuous stirring to get solution form. In another beaker sugar solution is prepared and transferred into the first beaker. Sweetening and flavouring agents were added and mixed thoroughly. The solution was transferred into moulds to avoid exposure to the outer environment. The formed jellies were stored in a dry place [20].

TABLE 4: FORMULATION TRIALS OF VARYING CONCENTRATION OF GELLING AGENTS

Ingredients	F1	F2	F3	F4	F5
Kalanchoe pinnata	100 mg	100 mg	100 mg	100 mg	100 mg
Cynodondactylon	100 mg	100 mg	100 mg	100 mg	100 mg
Tribulus terrestris	100 mg	100 mg	100 mg	100 mg	100 mg
Carrageenan	1%	1.25%	1.5%	1.75%	2.00%
Citric acid	1%	1%	1%	1%	1%
Sodium Benzoate	0.1%	0.1%	0.1%	0.1%	0.1%
Sugar Syrup	60%	60%	60%	60%	60%
Water	QS	QS	QS	QS	QS

Evaluation of Formulation:

Dissolution Test: The dissolution test was carried out using the paddle method with a stirring rate of 50 rpm at 37 °C. In 900 mL of Phosphate buffer pH 6.8 in dissolution apparatus (Electrolab). Phosphate buffer, pH 6.8, was prepared by mixing 250 mL of 0.2 M potassium dihydrogen phosphate solution with 118 mL of 0.2 M sodium hydroxide solution [21]. After 5, 10, 15, 20, 40, 60, and 90 min of stirring, an aliquot of 5 mL of the sample was pipetted out and filtered through a membrane filter of pore size 0.2 µm then replaced with the same amount of fresh dissolution media [22, 23]. The concentration of extracts was determined by UV spectrophotometer at λmax 268 nm and 238 nm.

Texture Analysis: Texture Profile Analysis (TPA) was carried out utilising a CT3 Texture Analyzer (Brookfield Laboratories, Middleboro, USA). This instrumental approach served as a robust method for evaluating the mechanical attributes of the prepared OMJ. Widely recognized as the "two-bite test," this procedure entails the controlled penetration of the probe into the sample twice, each time reaching a specific depth, before reverting to

its original position. This systematic approach allowed for a comprehensive examination of the sample's textural properties, providing valuable insights into its structural integrity and sensory attributes. Different texture parameters like hardness, cohesiveness, springiness, gumminess, chewiness were measured from the obtained force–time plots. The TA5 kind of texture analysis probe has a constant speed of 1.0 mm/s and a trigger load of 1 g. The target was 4 mm, and the test type was compression test. There were two cycles in all. The test took place over a total of 12 minutes and 27 seconds. There were 50.00 points per second of data.

***In-vitro* Assessment:**

Analysis of Lithotriptic Activity [24]:

Isolation of Egg Membrane: The semipermeable membrane of eggs, nestled between the calcified outer shell and the inner contents of albumin and yolk, played a central role in our experimental approach. The semipermeable membrane of egg was obtained by chemical decalcification process by immersing eggs in 2M HCl overnight. This treatment ensured complete removal of the calcified shell, leaving the semi-permeable membrane intact. Following decalcification, the eggs were thoroughly washed with distilled water to eliminate any residual traces of the Acid. With precision, a small aperture was made at the top of the egg using a sharp pointer, facilitating the complete expulsion of the inner contents from the decalcified egg. Subsequently, the egg membrane was rinsed with distilled water, ensuring its pristine condition.

To optimise the membrane's properties, it was then immersed in an ammonia solution for a 20 minutes period, maintaining a moist environment and to neutralise residual acid. Following this treatment, the membrane was rinsed once again with distilled water to remove any excess ammonia traces. Finally, the prepared egg membranes were stored in the refrigerator at 4-5 degree in phosphate buffer at a pH range of 6.8 to 7.00 to preserve their structural and functional integrity for subsequent experimentation.

Incubation of Extracts with Experimental Kidney Stones (Calcium Oxalate Crystal): 10 mg of calcium oxalate with 100 mg of each of three extracts in combination was delicately encased within semi-permeable membranes ensuring controlled interaction within the experimental milieu and suspended within a conical flask containing 100 ml of 0.1 M TRIS HCl buffer (pH=7). The samples were incubated at 37°C for a duration of 48 hours.100mg of standard Cystone with 10 mg of calcium oxalate was also treated in a similar manner as that of test extracts.

The experimental design encompassed three distinct groups. The first served as a negative control, consisting solely of 10 mg of calcium oxalate. The second group combined the calcium oxalate 10 mg with 100 mg of the standard compound (Cystone), while the third group employed calcium oxalate 10 mg.

HPLC Analysis: The literature lacks well-defined *in-vitro* techniques for accurately assessing lithotriptic effects. In this study, we aimed to develop a novel methodology for the estimation of calcium oxalate (CaOx) and to evaluate the lithotriptic efficacy of the test drug. Specifically, we established an innovative and previously unreported approach for CaOx quantification using high-performance liquid chromatography (HPLC) analysis.

In this study, we utilised HPLC to determine the level of calcium oxalate in the samples under investigation. The objective of the experiment was to quantitatively estimate the concentration of calcium oxalate in the provided samples using the Agres 1100 HPLC system. Two samples and one standard were prepared for analysis. A working standard solution ranging from 0 to 1000 micrograms per millilitre (µg/mL) was prepared in the base solution and filtered through a 0.22 micrometre syringe filter to ensure purity and uniformity.

The experiment began with the careful weighing of 10 mg of calcium oxalate, 100mg of each test drug and standard compound, Cystone. These components were delicately encased within semi-permeable membranes, ensuring controlled interaction within the experimental milieu. These were carefully packed together in a semi-permeable membrane, ensuring uniform distribution and minimal interference. Suspended within a conical

flask containing 100 ml of 0.1 M TRIS buffer, the samples were subjected to controlled conditions, with an incubator set at 37°C for a duration of 48 hours. After incubation for two days, 1 millilitre (mL) of the sample solution was collected from the buffer, assuming that calcium oxalate crystals would diffuse out from the semi-permeable membrane due to the influence of the drug. The collected sample was then filtered through a 0.22 micrometre filter to remove any particulate matter or impurities before injection into the HPLC system.

The HPLC analysis was performed using an Agress 1100 HPLC system equipped with a UV-Visible detector. The injection volume for each sample was 20 microliters (µL), and the run time was set to 15 minutes. Isocratic gradient conditions were employed with a mobile phase consisting of methanol: water (50% methanol + 50% water + 0.1% formic acid). The flow rate was maintained at 1.0 millilitre per minute (mL/min) to ensure optimal separation and elution of the analytes. The HPLC analysis revealed distinct peaks corresponding to the retention time of calcium oxalate in both the samples and the standard solution.

Microbial Assay: Individuals suffering from urolithiasis are more susceptible to urinary tract infections (UTIs). Consequently, evaluating the antimicrobial activities of various extracts is crucial in addressing this increased risk. This study focuses on assessing the efficacy of these extracts in combating UTI-causing pathogens in urolithiasis patients.

Anti-bacterial and anti-fungal activity of the phytochemical extracts has been tested using the Agar well-diffusion method. Nutrient broth/agar was used to cultivate bacteria [25]. *Escherichia coli*, *Staphylococcus aureus* were the bacteria used and *Candida albicans* was the fungi used. These microbes are the causative agents in most of the cases of urinary tract infections (UTI).

A 20 ml of molten nutrient agar media has been added into sterilised Petri-plates [26]. Agar plates were prepared and 0.1 ml volume of each diluted microbial isolates was transferred into the agar plates. The inoculated agar plates were kept for 30 min for the isolate to diffuse appropriately into the medium [27]. A 5 mm sterile cork borer was used to bore wells on the medium 0.1 ml volume of the K. pinnata extract and Wells are loaded with 100 mg/ml conc. of extract suspended in distilled water. The agar plates were labelled accordingly [27]. For 24 hrs the plates have been incubated at a temperature of 37C [26]. The Cystone tablet from Himalaya Drug Company was employed as a positive control as well as wells loaded with sterile water were used as a negative control. The inoculated agar plates were incubated properly and viewed for the diameter of inhibition zones. The diameter of inhibition zones was suggested by clear areas without growth around the well.

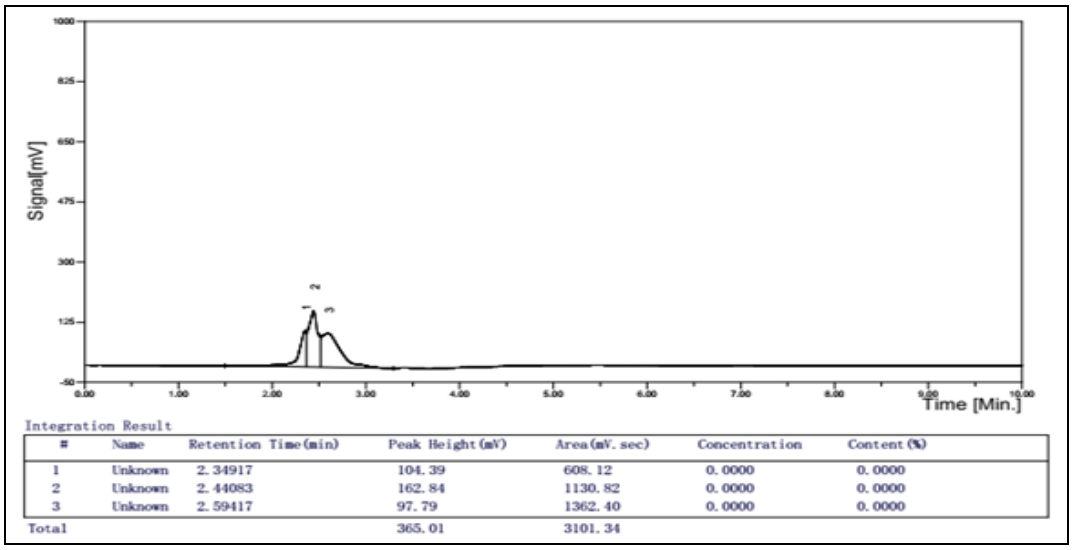
RESULT AND DISCUSSIONS:

HPLC Analysis:

Standards Analysis of HPLC: At a concentration of 10 micrograms per millilitre (µg/mL), no discernible peak was observed, indicating a sub-threshold concentration insufficient for detection under the specified chromatographic conditions. A standard solution of 100 µg/mL manifests a distinct peak at a retention time of 2.43667 minutes, with a corresponding peak area of 796.34. This observation corroborates the presence of the target compound at an intermediate concentration, indicative of its chromatographic detectability within the specified concentration range. Upon elevating the concentration to 1000 µg/mL, a prominent peak emerged at a retention time of 2.32833 minutes, exhibiting a substantially amplified peak area of 14215.58. This heightened peak intensity underscores the increased abundance of the target compound within the analytical matrix, affirming its robust detection at higher concentrations [28].

Sample Analysis of HPLC: The standard marketed preparation, boasting a concentration of 1000 µg/mL, yielded a discernible peak at a retention time of 2.44083 minutes, accompanied by a peak area of 1130.82. This chromatographic signature aligns with the expected behaviour of a standard solution, reaffirming the fidelity of the analytical method employed. In contrast, the test drug sample, also prepared at a concentration of 1000 µg/mL, exhibited a distinct peak at a retention time of 2.28417 minutes, characterised by a peak area of 1448.66.

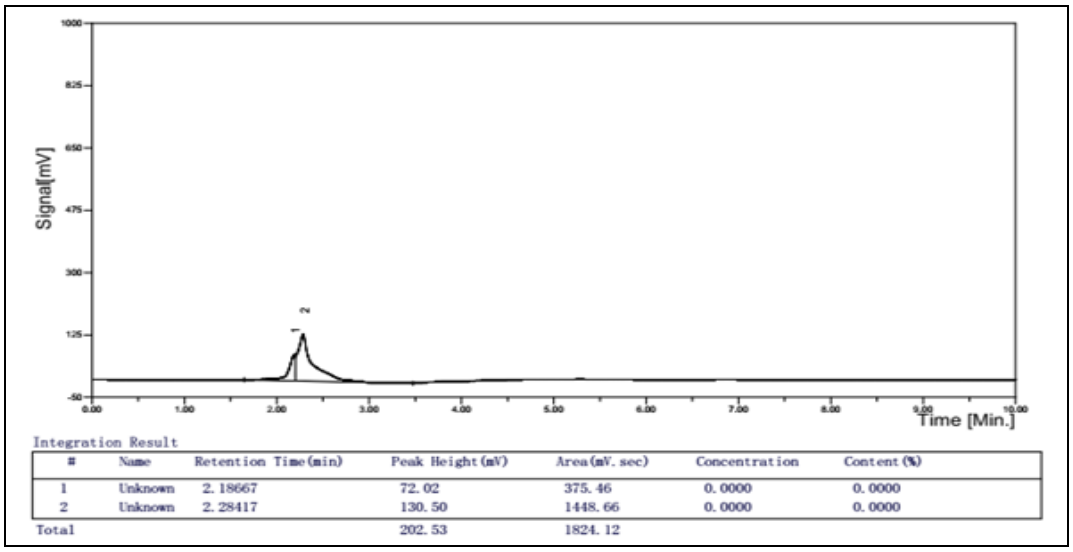
Notably, the observed retention time deviates slightly from the standard marketed preparation, indicative of potential variations in compound composition or formulation [28].



Integration Result

#	Name	Retention Time(min)	Peak Height(mV)	Area(mV. sec)	Concentration	Content(%)
1	Unknown	2. 34917	104. 39	608. 12	0. 0000	0. 0000
2	Unknown	2. 44083	162. 84	1130. 82	0. 0000	0. 0000
3	Unknown	2. 59417	97. 79	1362. 40	0. 0000	0. 0000
Total			365. 01	3101. 34		

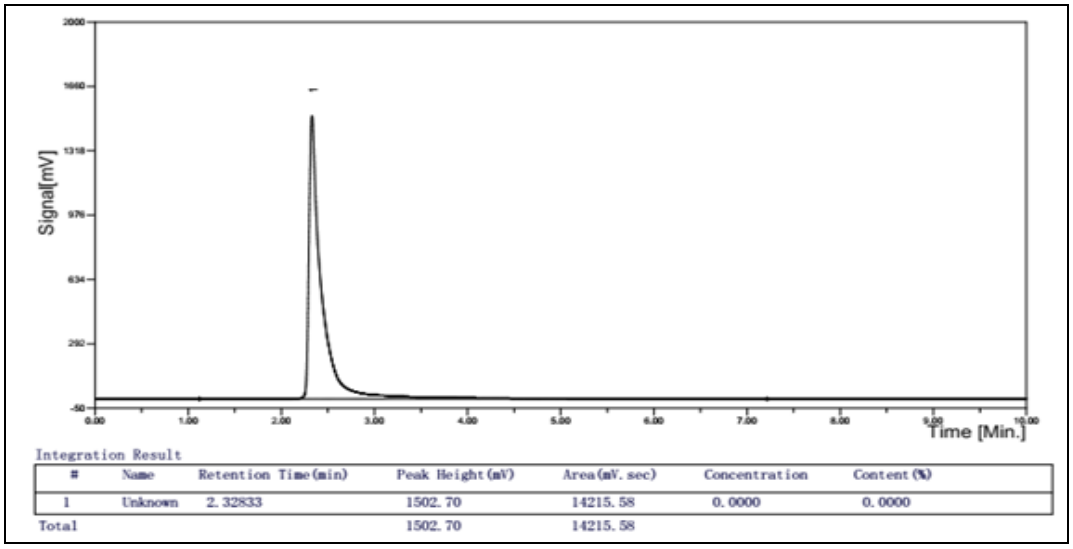
FIG. 1: REFERENCE FORMULATION ACTIVITY OF CYSTONE (STANDARD: BLUE CAP)



Integration Result

#	Name	Retention Time(min)	Peak Height(mV)	Area(mV. sec)	Concentration	Content(%)
1	Unknown	2. 18667	72. 02	375. 46	0. 0000	0. 0000
2	Unknown	2. 28417	130. 50	1448. 66	0. 0000	0. 0000
Total			202. 53	1824. 12		

FIG. 2: SAMPLE NAME – TEST GROUP ACTIVITY OF POLYHERBAL OMJ (TEST: RED CAP)



Integration Result

#	Name	Retention Time(min)	Peak Height(mV)	Area(mV. sec)	Concentration	Content(%)
1	Unknown	2. 32833	1502. 70	14215. 58	0. 0000	0. 0000
Total			1502. 70	14215. 58		

FIG. 3: STANDARD CALCIUM OXALATE 1000 µG/ML

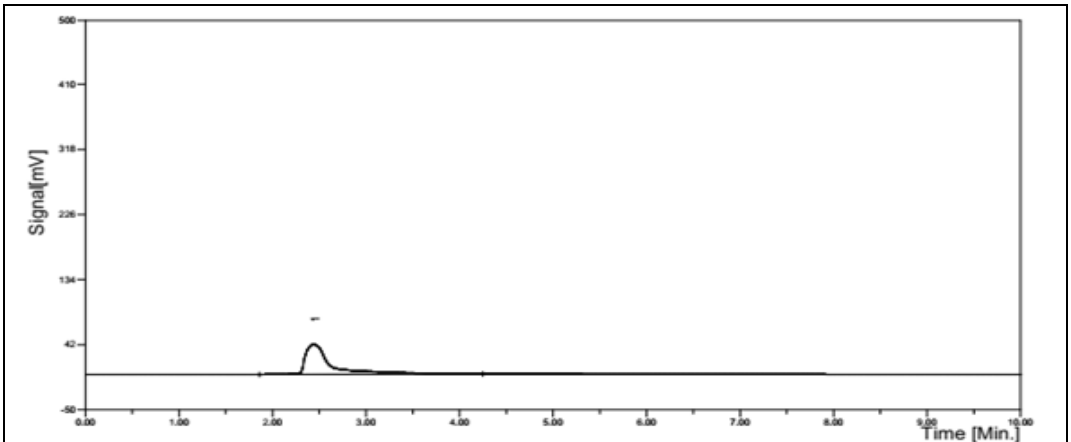


FIG. 4: STANDARD CALCIUM OXALATE 100 µG/ML

Dissolution Test: The dissolution test serves as a pivotal component in assessing the release kinetics of pharmaceutical formulations, shedding light on the propensity of a drug to liberate from its dosage form over time.

In our investigation, we conducted a dissolution test for the formulated drug, monitoring its absorbance at wavelengths of 268 nm and 238 nm, with the respective readings depicted below:

TABLE 5: DISSOLUTION TIME AND OBSERVED ABSORBANCE OF THE ORALLY MEDICATED JELLIES

Time (min)	Absorbance at 268 nm	Absorbance at 238 nm
5	0.0421	0.0340
15	0.0560	0.0308
20	0.0811	0.0652
40	0.0914	0.0686
60	0.1469	0.1345
90	0.1652	0.1649

The dissolution profile, as delineated by the absorbance readings at 268 nm and 238 nm, portrays a discernible trend over the experimental time frame [29]. Notably, there is a progressive augmentation in absorbance values at both wavelengths with increasing time intervals, indicative of a concurrent increase in drug concentration within the dissolution medium.

This progressive escalation in absorbance, culminating in maximal readings at the 60 and 90-minute junctures, underscores the gradual and time-dependent release kinetics inherent to the formulation under scrutiny [29, 30]. The convergence of absorbance trends across both wavelengths underscores the robustness and consistency of our experimental observations, fortifying the veracity of our analytical approach. In summation, the dissolution test elucidates a concerted and time-dependent release of the drug from its formulation, thereby furnishing invaluable insights into its dissolution kinetics and therapeutic efficacy. These findings hold significant implications for pharmaceutical formulation design and optimization, facilitating informed decision-making in drug development endeavours.

Texture Analysis [31, 32]: In our investigation, we subjected the sample to comprehensive texture analysis, encompassing parameters such as hardness, cohesiveness, springiness, gumminess, chewiness, and pH.

Hardness: The sample exhibited a hardness value of 518 grams, indicative of its resistance to deformation or breakage under applied force. This parameter serves as a crucial determinant of textural quality, with higher hardness values often correlating with perceived firmness and structural integrity.

Cohesiveness: A cohesiveness value of 0.83 was observed, highlighting the sample's ability to

maintain its internal structure upon deformation. Cohesiveness reflects the degree of internal bonding within the sample, with higher values suggestive of enhanced structural resilience and mouthfeel.

Springiness: The sample displayed a springiness value of 36.70, denoting its propensity to regain its original shape following deformation.

Springiness underscores the elasticity of the sample, offering insights into its resilience and bounce-back characteristics upon mechanical manipulation.

Gumminess: With a gumminess value of 431.00 grams, the sample exemplified its chewy and adhesive nature. Gumminess quantifies the energy required to disintegrate the sample during mastication, with higher values indicative of increased chewiness and oral adhesiveness.

Chewiness: The sample exhibited a chewiness value of 155.00 millijoules (mJ), underscoring its textural complexity and resistance to breakdown during mastication. Chewiness amalgamates the concepts of hardness and gumminess, encapsulating the overall effort required to masticate the sample into a swallow able consistency.

pH: The pH value of the sample was measured at 4.5, serving as a crucial determinant of its acidity or alkalinity. pH exerts a profound influence on the sensory attributes and stability of food products, with deviations from optimal pH ranges potentially impacting flavour, texture, and shelf-life.

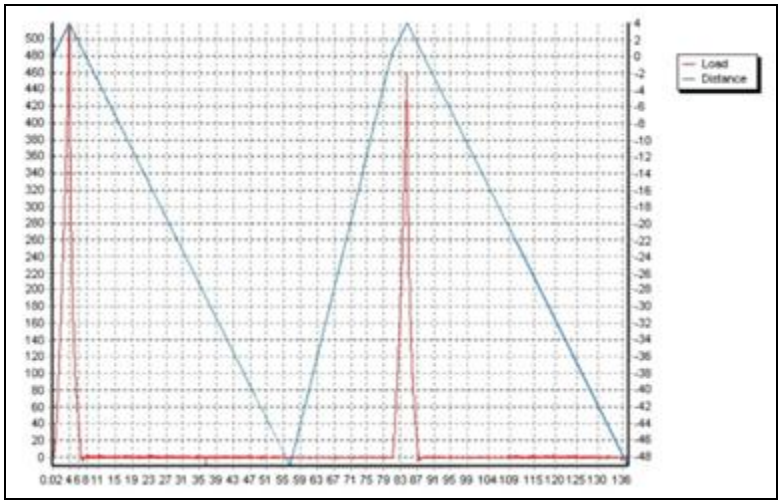


FIG. 5: TEXTURE ANALYSIS GRAPH

Cohesiveness and springiness, reflective of the sample's internal integrity and elasticity, contribute to its mouth feel and sensory appeal, ensuring a pleasurable eating experience characterised by tactile satisfaction and resilience. The pronounced gumminess and chewiness underscore the sample's adhesive and chewy nature, endowing it with a distinctive textural complexity that may evoke sensory intrigue and prolong oral processing. Furthermore, the measured pH value assumes significance in elucidating the sample's acidity level, with potential ramifications for flavour perception, microbial stability, and shelf-life.

Anti Microbial Assay: The antimicrobial activity of *Kalanchoe pinnata* (*K. pinnata*) extract was evaluated using the agar well-diffusion method. The extract's efficacy was tested against *Escherichia coli*, *Staphylococcus aureus*, and *Candida albicans*, which are common causative agents of urinary tract infections (UTIs). The zones of inhibition, representing the antimicrobial effectiveness of the *K. pinnata* extract, were measured and compared to those of a positive control (Cystone tablet) and a negative control (sterile water).

The largest zone of inhibition (2.08 cm) was observed against *E. coli*, indicating strong antibacterial activity. *E. coli* is a common pathogen in UTIs, and the significant inhibition zone suggests that *K. pinnata* extract could be a potent alternative or adjunctive treatment for *E. coli*-induced UTIs. The zone of inhibition against *S.*

aureus was 1.0 cm. Although smaller than that observed for *E. coli*, this inhibition is still notable. *S. aureus* is a less frequent but possible cause of UTIs. The moderate activity against this bacterium suggests that while *K. pinnata* extract has some efficacy, it may be more potent against gram-negative bacteria like *E. coli*. The extract showed a zone of inhibition of 1.9 cm against *C. albicans*, indicating substantial antifungal activity. *C. albicans* is a common fungal pathogen in UTIs, particularly in patients with complicated infections or those who are immunocompromised. The results suggest that *K. pinnata* extract could be beneficial in managing fungal UTIs [32, 33].

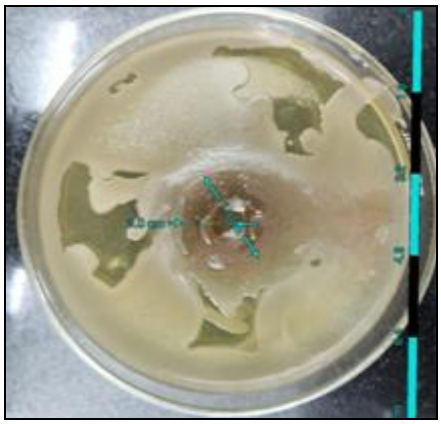


FIG. 6: ZONE OF INHIBITION OF *CANDIDA ALBICANS*

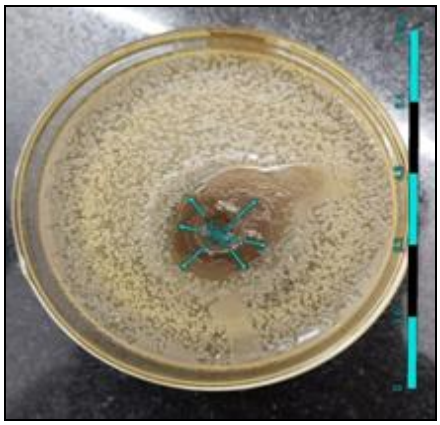


FIG. 7: ZONE OF INHIBITION OF *E. COLI*

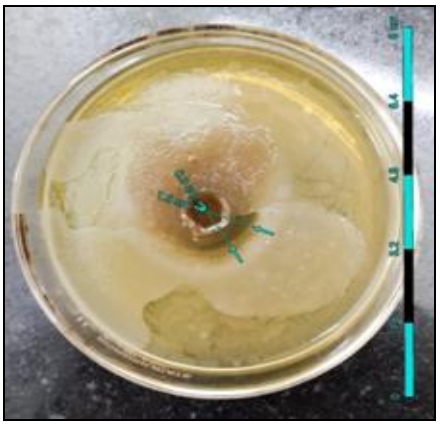


FIG. 8: ZONE OF INHIBITION OF *STAPHYLOCOCCUS AUREUS*

The use of Cystone tablets as a positive control validates the methodology, as Cystone is known for its antimicrobial properties. The absence of zones of inhibition around the wells containing sterile water confirms that the observed antimicrobial activity is due to the *K. pinnata* extract.

CONCLUSION: The comprehensive investigation conducted in this study provides significant insights into the chromatographic, dissolution, textural, and antimicrobial characteristics of the tested compounds and formulations. HPLC analysis demonstrated the detectability of the target compound across a broad concentration range, establishing the method's sensitivity and linearity. The dissolution profile indicated a time-dependent release of the drug, confirming the formulation's efficacy for sustained therapeutic delivery. Texture analysis revealed significant hardness, cohesiveness, springiness, gumminess, and chewiness, contributing to the sample's overall quality, with a pH value of 4.5 supporting microbial stability and sensory attributes. The *Kalanchoe pinnata* (*K. pinnata*) extract exhibited notable antimicrobial activity, particularly against E. coli, highlighting its potential as an alternative or adjunctive treatment for UTIs. These findings have critical implications for pharmaceutical formulation and drug development, emphasising the need for a multifaceted approach to ensure efficacy, quality, and therapeutic potential. Further research is recommended to optimize formulations and explore additional therapeutic applications.

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