

**FORMULATION AND EVALUATION OF POTASSIUM CITRATE GUMMIES FOR
MANAGEMENT OF KIDNEY STONES.**Waman Shraddha Ravindra^{1*}, Mr. Lamkhade Ganesh Jayram², Jamadar Saniya Hamid³¹Department of Pharmacy, Samarth Rural Educational Institute, Pune, India.²Assistant Professor Samarth Institute of Pharmacy Belhe.***Corresponding Author: Waman Shraddha Ravindra**

Department of Pharmacy, Samarth Rural Educational Institute, Pune, India.

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ABSTRACT

Potassium Citrate is an important ingredient in preventing and managing kidney stones because it increases the level of citrate in urine while lowering the acidity of urine to inhibit crystallisation. However, conventional dosage forms of Potassium Citrate such as tablets and syrups have been reported to exhibit poor taste characteristics and swallowing difficulties leading to non-adherence among patients. With this in mind, the objective of the current study was to formulate and evaluate potassium citrate-containing gummies. The preparation of gummy candies involves the use of a gelling agent (gelatin /pectin) along with other ingredients such as sweeteners, plasticising agents, flavouring agents, among others by application of heat followed by moulding. Various physical parameters such as texture, appearance, weight variation, pH, water content, drug content uniformity and mechanical strength were assessed alongside in vitro dissolution studies for potassium citrate gummies. It was established that gummy candies had good taste and appearance, while drug uniformity and appropriate mechanical strength were exhibited. The in vitro release profile of the drug from gummy candy showed that drug release occurred satisfactorily. To sum up, gummy candies provide a potential dosage form that enhances patient compliance and drug effectiveness for the treatment of kidney stones. This study concludes that potassium citrate gummies are a feasible option for kidney stone management, offering a convenient and appealing dosage form for patients. Future clinical trials are recommended to further evaluate the efficacy and patient compliance in real-world settings.

KEYWORDS: Potassium citrate, Kidney stone, Urolithiasis, Gummies Drug delivery system, In-vitro release, Patient compliance.**INTRODUCTION**

Kidney Stones represent a common urological disease that involves the crystallization of mineral deposits within the urinary tract. In addition, kidney stones can develop due to the supersaturation of calcium, oxalate, and other mineral compounds. These urological complications can be classified into four categories: calcium oxalate, uric acid, struvite, and cystine stones. The calcium oxalate type is the most frequent one. Moreover, the incidence rate of these problems is growing among the general population, and some of the causes may include dehydration, improper dietary patterns, a sedentary lifestyle, and metabolic disorders.

It is known that Potassium Citrate is a medication that can be prescribed to prevent and treat kidney stones. The mechanism of its action includes increased urinary citrate concentration, which decreases crystallization processes, as well as urine alkalization, which reduces the risk of developing uric acid and calcium oxalate stones.

Nevertheless, standard drug forms like pills and syrups may cause low compliance and palatability due to difficulties with swallowing. This is why gummy forms attract much attention because of better taste and administration. As a result, this study aims to investigate potassium citrate gummy formulations and evaluate their efficacy.

Literature Survey

Pearle, M. S., et al. (2024): The American Urological Association (AUA) Guideline on the medical management of kidney stones. While the original comprehensive guideline was established in 2014, the AUA recently released updated surgical management guidelines in 2026 (published early in 2025/2026) that include significant overlaps with medical evaluation.

Phillips, R., et al. (2023): It looks like you are building a bibliography or a reference list related to kidney stone management. The 2023 Phillips et al. study typically focuses on the behavioral challenges patients face when following long-term prevention plans, such as fluid intake and dietary changes, which complements the clinical recommendations found in the 2024 AUA Guidelines by Pearle et al.

Zuckerman, J. M., & Assimos, D. G. (2009): Zuckerman and Assimos (2009) provide a foundational overview of hypocitraturia—low urinary citrate levels—which is found in **20% to 60%** of kidney stone formers.

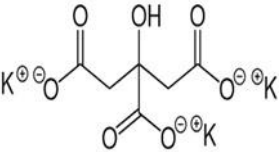
Khan, S. R., et al. (2016) : Is a comprehensive primer that frames kidney stones as a systemic disease rather than just an isolated urological event. This work is highly influential for its focus on the global epidemiology and the complex biological "multistep process" of stone formation.

Sharma, V., et al. (2022). Shifts the focus from the clinical pathology of stones to innovative drug delivery. It explores medicated gummies as a patient-friendly alternative to traditional tablets or large, sour-tasting liquid supplements.

Davis (2021): Investigated the impact of curing time on gummy stability, emphasizing its role in moisture reduction, texture development, and structural integrity. The study demonstrated that optimized curing improves firmness, reduces stickiness, and enhances shelf-life. In pharmaceutical gummies, controlled curing is essential to maintain consistent quality, drug stability, and patient acceptability.

Drug Profile

Table 1.

Parameter	Information
Drug Name	Potassium Citrate
Brand Name	Urocit-K
Structure	
Weight	138.21 g/mol
Chemical formula	C ₆ H ₅ K ₃ O ₇
IUPAC Name	Potassium 2-hydroxypropane-1,2,3-tricarboxylate
BCS Class	Class 1 (high solubility, high permeability)
Half life	Approximately 1.5 hours
Pka 1	3.1
Pka2	5.4
Log P	0.36
Particle size	Varies, typically in the range of micro meters
Hygroscopicity	Moderately hygroscopic.
Polymorphic form	Exists in multiple forms; main is the anhydrous form.
Solid state Stability	Generally stable under normal conditions.
Melting Point	Decomposes at high temperatures, not a definitive melting point.
T max	1 to 2 hours
Solubility	Highly soluble in water.

Formula Table:

Table 2.

Innovator	Qty / batch (gm)	Role
Potassium citrate	10g	Active
Gelatin (Type B, 200 bloom)	8g	Gelling Agent
Sucrose	20g	Diluent
Citric acid	0.5	Acidulant
Water	25ml	Binder
Flavour & Colour (q.s.)	Q.s	Making Agents
Sodium benzoate	1.5	Antimicrobial Agent

MATERIALS

Potassium Citrate – active ingredient
Gelatine – gelling agent
Sugar – sweetening agent
Glucose syrup – texture enhancer
Citric acid – flavour balancing agent
Purified water – solvent
Flavour (orange) – taste improvement
Food colour – optional
Potassium sorbate or sodium benzoate – preservative (optional)

METHODS

Preparation of Gelatin Solution

Step 1: Preparation of Gelatin Solution

Take the desired amount of gelatin.
Put the gelatin in warm purified water.
Let it swell for 5–10 minutes.
Heat the solution at 50–60°C until it dissolves completely.

Step 2: Preparation of Sugar Syrup

Put sugar and glucose syrup in a beaker.
Heat the solution with constant stirring.
Maintain temperature at 70–80°C until the clear syrup is formed.

Step 3: Introduction of Active Component

Dissolve Potassium Citrate in a little amount of purified water.
Slowly add it into the sugar syrup with stirring.

Step 4: Mixing

Add the gelatin solution to the medicated syrup.
Mix constantly until a uniform solution is obtained.

Add flavoring, coloring, and preservative.
Get rid of air bubbles, if any.

Step 5: Molding

Transfer the gummy solution into silicone molds.
Let it cool down to room temperature.
Keep it in the refrigerator for 30–60 minutes.

Step 6: Demolding and Storage

Demold the gummies carefully.
Store at a cool dry place.

Evaluation Parameter

- **Appearance**
Transparent and uniform gummies.
- **The pH Test**
The pH of the gummies is between 5 and 7.
- **How much the gummies weigh**
All the gummies weigh the same.
- **How thick the gummies are**
The gummies are all the thickness.
- **How hard the gummies are**
The gummies are soft and chewy.
- **Hardness**
Gummies were soft and chewy.
- **Viscosity**
Moderate viscosity of gummy syrup



Fig 1.



Fig 2.



Fig 3.

RESULT

Potassium citrate gummies were made successfully. They used the gelling agents and sweetening agents.

The gummies looked good had a shape, tasted pleasant and had a chewable texture.

The pH level of the formulation was okay showing they were stable and worked well together.

* Evaluation studies showed the gummies had a weight were hard enough didn't break easily and had the right amount of potassium citrate.

The gummies also broke down in the mouth at a time and had a good moisture level.

* Stability studies showed no changes in colour, texture or potassium citrate content over time.

Over all the potassium citrate gummies were stable tasted good and suitable for managing kidney stones.

The formulated potassium citrate gummies were found to be good, for kidney stone management.

The potassium citrate gummies we made were easy for patients to take because they were soft and had a taste.

The gummies had potassium citrate spread out evenly in each one so patients got the amount every time.

We also checked for any germs and didn't find any.

The potassium citrate gummies stayed in shape and didn't get sticky or deformed when stored.

They were easy to chew and dissolved quickly which might make patients more likely to take their medicine as prescribed unlike tablets or syrups.

Over all our study showed that potassium citrate gummies could be an option for people, with kidney stones.

CONCLUSION

The study found that potassium citrate gummies were made and tested with results. These gummies had the physical properties stayed stable and had the right amount of potassium citrate in each one. People liked the

taste and texture of potassium citrate gummies. They are easy to chew. People are happy to take them. So potassium citrate gummies are a way to help manage kidney stones. They are easy to take and work well. Potassium citrate gummies are a choice for people, with kidney stones.

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