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NOVEL APPROACH TO CALCIUM SUSPENSION FORMULATION USING HPMC AND HERBAL ADDITIVES

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Abstract

Calcium is an essential mineral required for bone formation, muscle contraction, nerve transmission, and blood clotting. Calcium deficiency can lead to osteoporosis, rickets, and other bone disorders. Oral calcium supplements are commonly used to prevent and treat calcium deficiency. Suspensions are an important dosage form used when the drug is poorly soluble in water. This project focuses on the formulation and evaluation of a calcium supplement suspension using Calcium Carbonate as the active pharmaceutical ingredient (API). The study includes the preparation method, role of excipients, formulation steps, evaluation parameters, stability considerations, and advantages of suspension dosage forms. The developed suspension aims to provide improved palatability, uniform dosing, and ease of administration, particularly for pediatric and geriatric patients.

Keywords: calcium carbonate suspensions, HPMC, Tulsi, Sodium benzoate, Glycerine, Sorbitol.

Introduction

Calcium is an essential mineral that plays a vital role in maintaining human health and is the most abundant mineral in the body. Approximately 99% of total body calcium is stored in bones and teeth, where it provides structural strength, while the remaining 1% is present in blood and soft tissues, contributing to important physiological functions such as muscle contraction, nerve transmission, and blood clotting. Due to its importance, calcium supplementation is widely used to maintain adequate levels in individuals who do not obtain sufficient calcium through their diet. Oral suspensions are liquid dosage forms in which finely divided solid particles are dispersed in a liquid medium, making them particularly suitable for drugs that are poorly soluble in water. Calcium carbonate is one of the most commonly used calcium supplements because of its high elemental calcium content, affordability, and widespread availability. The formulation of pharmaceutical suspensions requires careful consideration to ensure uniform distribution of particles, physical stability, and patient acceptability. This is achieved by incorporating suitable excipients such as suspending agents, preservatives, sweeteners, and flavoring agents. The present work focuses on the design and development of a stable and effective calcium carbonate suspension intended for oral administration.

Calcium supplementation has become a common practice across various age groups and is widely promoted for improving bone density and overall skeletal health. Public perception often favors calcium as universally beneficial, supported by clinical guidelines and strong marketing, leading to its extensive use among children,

adults, and the elderly. Many individuals are unable to meet their daily calcium requirements through diet alone due to limited consumption of calcium-rich foods or dietary habits, making supplementation necessary in such cases. Earlier research suggested that dietary calcium might be more effective than supplemental calcium because of better absorption; however, current evidence remains inconclusive, and further studies are needed to clarify their comparative effectiveness in improving bone health. In recent years, concerns have been raised regarding the safety of excessive or indiscriminate calcium supplementation. Some studies and meta-analyses indicate that supplementation may not significantly reduce fracture risk among older adults, while others suggest a possible association between high calcium intake and an increased risk of cardiovascular diseases, particularly in men. Additionally, excessive calcium intake may lead to adverse effects such as kidney stones and gastrointestinal disturbances. Therefore, although calcium supplementation is beneficial for individuals with inadequate dietary intake, its use should be carefully considered by weighing potential benefits against possible health risks.

Materials Required

Active Ingredient:

Calcium Carbonate Excipients:

HPMC (Suspending Agent)
Sorbitol (Sweetening Agent)
Glycerin (Wetting Agent)
Sodium Benzoate (Preservative)
Flavoring Agent (Orange and Tulsi extract)
Purified Water (Vehicle)

Equipment:

Beaker
Glass rod
Measuring cylinder
Electronic balance
Mortar and pestle Magnetic stirrer pH meter
Viscometer

Role of Ingredients

Calcium Carbonate: It is the active pharmaceutical ingredient providing calcium supplementation.

HPMC: It acts as a suspending agent that increases viscosity and prevents sedimentation of particles.

Sorbitol: It improves taste and provides sweetness to make the formulation palatable.

Glycerin: It acts as a wetting agent that helps disperse calcium carbonate particles evenly.

Sodium Benzoate: It acts as a preservative to prevent microbial contamination.

Flavoring Agent: It improves patient acceptance of the product.

Purified Water: It acts as the vehicle or dispersion medium.

Formulation Table

Ingredient | Quantity (for 100 mL)
Calcium Carbonate | 10 g
HPMC| 0.5 g
Sorbitol | 10 mL
Glycerin | 5 mL
Sodium Benzoate | 0.1 g
Flavor | q.s.(Orange,Tulsi) Purified Water | up to 100 mL

Method of Preparation

1. Accurately weigh all ingredients using an electronic balance.

2. Measure required liquids using a measuring cylinder.

Preparation of HPMC Dispersion

1. Take about 20-30 mL purified water and heat it to about 70-80°C
2. Slowly sprinkle HPMC into the hot water while stirring continuously
3. Continue stirring to avoid lump formation,
4. Allow the mixture to cool and add a smal amount of cold water to hydrate HPMC completely.
5. A smooth viscous solution will form.

Preparation of Calcium Carbonate Paste

1. Take calcium carbonate powder in a mortar.
2. Triturate the powder to obtain a fine particle size.
3. Add glycerin slowly while triturating to form a smooth paste
4. This step acts as wetting of the powder and prevents floating of particles.

Mixing of Suspension Base

1. Gradually add the prepared HPMC solution into the calcium carbonate paste
2. Triturate continuously to obtain a uniform dispersion.
3. Ensure that the solid particles are evenly distributed.

Addition of Sweetener and Preservative

1. Dissolve sodium benzoate in a small Quantity of purified water
2. Add this solution into the mixture and stir Properly.
3. Add sorbitol solution to improve sweetness And palatability.

Addition of Flavor

1. Added the required flavoring agent (orange and Tulsi).
2. Mix thoroughly to distribute flavor evenly in the formulation.

Make up the Final Volume

1. Transfer the mixture to a measuring cylinder or beaker.
2. Add purified water gradually while stirring.
3. Make up the final volume to 100 mL

Active Pharmaceutical Ingredient (API)

➢ Calcium Carbonate

1. Role in the Formulation

Calcium carbonate acts as the active pharmaceutical ingredient (API) in the suspension. Its main role is to supply elemental calcium to the body. It is used in oral formulations to prevent or treat calcium deficiency and bone-related disorders such as osteoporosis and rickets.

2. Significance

Calcium carbonate contains about 40% elemental calcium, which makes it one of the most efficient and economical sources of calcium in pharmaceutical formulations. It is widely used in tablets, suspensions, and chewable preparations. In suspension form, it becomes easier to administer to pediatric and geriatric patients who may have difficulty swallowing tablets.

3. Mode of Action

After oral administration, calcium carbonate reacts with gastric hydrochloric acid in the stomach to form calcium chloride, water, and carbon dioxide. The calcium ions released are then absorbed in the small intestine and utilized in the body for bone mineralization, muscle contraction, nerve transmission, and blood clotting.

Calcium Carbonate powder

4. Advantages

- High calcium content (about 40% elemental calcium)
- Cost-effective and widely available
- Suitable for long-term calcium supplementation
- Effective for bone health and prevention of osteoporosis
- Can also act as a mild antacid

Suspending Agent

➢ Hydroxypropyl Methylcellulose

1. Role in the Formulation

HPMC functions as a suspending agent in the formulation. It increases the viscosity of the liquid medium, which helps keep the calcium carbonate particles uniformly dispersed throughout the suspension and prevents rapid sedimentation.

Hydroxypropyl Methylcellulose

Significance

Suspending agents are essential for maintaining physical stability in suspensions. Without them, the insoluble particles would quickly settle at the bottom of the container, leading to uneven dosing. HPMC ensures that the suspension remains homogeneous and easy to redisperse upon shaking.

2. Mode of Action

HPMC hydrates in water and forms a colloidal viscous solution. This viscous network slows down the movement of dispersed particles according to Stokes' law, thereby reducing the rate of sedimentation and maintaining uniform distribution.

3. Advantages

- Provides excellent viscosity and stability
- Non-toxic and safe for oral use
- Compatible with many pharmaceutical ingredients
- Improves redispersibility of the suspension

Wetting Agent

➢ Glycerin

1. Role in the Formulation

Glycerin acts as a wetting agent that helps disperse calcium carbonate powder in the liquid medium. It prevents the formation of floating particles and allows the powder to mix easily with the suspension base

2. Significance

Many insoluble powders tend to float on the surface of water due to trapped air around particles. Glycerin reduces this effect and helps the powder become properly wetted, ensuring uniform mixing and preventing aggregation.

3. Mode of Action

Glycerin reduces the surface tension between the powder and the liquid medium, allowing the liquid to penetrate the particles more easily. This improves dispersion and ensures better suspension stability.

4. Advantages

- Improves wetting and dispersion of powders
- Slightly sweet taste that improves palatability
- Non-toxic and widely used in oral formulations
- Acts as a mild humectant

Glycerin

Sweetening Agent

➢ Sorbitol

1. Role in the Formulation

Sorbitol is used as a sweetening agent to improve the taste of the suspension. Since calcium carbonate has a slightly chalky taste, sorbitol makes the formulation more palatable.

2. Significance

Taste is a very important factor in oral liquid formulations, especially for children and elderly patients. Sorbitol improves patient compliance by masking unpleasant taste and providing mild sweetness.

3. Mode of Action

Sorbitol interacts with taste receptors on the tongue, producing a pleasant sweet taste. It also increases the viscosity slightly, contributing to better mouthfeel.

4. Advantages

1. Provides sweetness without causing dental caries
2. Safe for oral pharmaceutical use
3. Improves taste and patient acceptance
4. Also acts as a humectant

Preservative

➢ Sodium Benzoate

1. Role in the Formulation

Sodium benzoate acts as a preservative that prevents microbial growth in the aqueous suspension during storage.

2. Significance

Since suspensions contain water, they are prone to microbial contamination. The preservative helps maintain the safety and shelf life of the formulation by inhibiting the growth of bacteria, yeast, and fungi.

3. Mode of Action

In acidic conditions, sodium benzoate converts to benzoic acid, which penetrates microbial cell membranes and interferes with their metabolic processes, ultimately inhibiting their growth.

Sodium benzoate

4. Advantages

1. Effective antimicrobial preservative

2. Works well in acidic formulations

3. Low concentration required

4. Widely used in pharmaceutical and food products

Vehicle

➢ Purified Water

1. Role in the Formulation

Purified water acts as the vehicle or dispersion medium in which the solid particles of calcium carbonate are suspended.

2. Significance

It provides the liquid base for the suspension and allows uniform distribution of all ingredients.

3. Mode of Action

Water acts as a solvent and dispersion medium, allowing excipients to dissolve and solid particles to remain suspended.

4. Advantages

1. Easily available

2. Compatible with most pharmaceutical ingredients

3. Suitable for oral liquid formulations

Evaluation of Suspension

The prepared suspension must be evaluated using the following parameters:

Sedimentation Volume:
It measures the degree of sedimentation of particles in suspension over time.

Redispersibility:
The ability of sedimented particles to redisperse upon shaking.

pH Measurement:
The pH of suspension should be within acceptable limits for oral administration.

Viscosity:
Viscosity affects the stability and pourability of suspension.

Particle Size Analysis:
Uniform particle size ensures stability and consistent dosing.

Physical Appearance:
Color, odor, and texture are evaluated to ensure acceptable product quality.

Advantages of Suspension Dosage Form

1. Suitable for poorly soluble drugs.
2. Easy administration for children and elderly patients.
3. Improved drug stability compared to solutions.
4. Flexible dosage adjustment.
5. Better palatability with sweeteners and flavors.

Disadvantages

1. Sedimentation of particles may occur.
2. Requires shaking before use.
3. Stability problems may arise during long storage.
4. Bulky packaging compared to tablets.

Evaluation Tests of Suspension:

➢ Appearance:

Observation: Smooth, white, aqueous suspension

Result: No visible aggregation or crystal growth

Conclusion: Acceptable.

➢ Sedimentation Volume (F):

Formula:

F = Vu / Vo

Initial volume (Vo) = 100 mL

Ultimate sediment volume (Vu) = 85 mL

Calculation: F = 85 / 100 = 0.85

Result: Good sedimentation volume

Conclusion: Indicates good stability Redispersibility Test:
Method: Shake the container manually

Observation: Sediment redistributes completely after 3–4 shakes

Result: Easily redispersible Conclusion: Pass.

➢ pH Determination:

Observed pH: 8.2

Conclusion: Suitable for calcium carbonate suspension (slightly alkaline)

➢ Viscosity:

Measured using Brookfield viscometer

Observed viscosity: 320 cps

Conclusion: Adequate viscosity for suspension stability and pourability.

➢ Particle Size Analysis:

Observed range: 1–10 µm

Conclusion: Fine particles ensure uniform dispersion.

➢ Density:

Method Used: Density Bottle (Pycnometer Method)

Weigh Empty Bottle, Clean and dry the density bottle

Weigh it using a digital balance. Weight of empty bottle (W_1) = 25.00 g

Weigh Bottle with Suspension:

Fill the bottle completely with your calcium suspension. Ensure no air bubbles. Wipe outside and weigh.

Weight of bottle + suspension (W_2) = 36.50 g

Find Weight of Suspension

Weight of suspension

$=W2-W1$

Weight of suspension$=W2-W1$

$=36.50-25.00=11.50g$.

Note Volume of Bottle

Standard density bottle volume = 10 mL (10 cm^3).

Calculate Density

Density=Volume/Mass

$=11.50/10=1.15g/cm^3$

Pure water density = 1 g/cm^3

our suspension contains: Calcium carbonate (heavy solid particles) Suspending agents

These increase the mass per unit volume

So density becomes greater than water

- Pourability.

Method: Suspension poured from measuring cylinder

Result: Balanced viscosity → smooth flow

No clogging → proper formulation

Observation: Easy and uniform flow

- Drug Content Uniformity

Method:

Assayed using titration method (or spectrophotometry)

Procedure: Known volume of suspension taken

Calcium estimated using complexometric titration (EDTA) Compared with standard

Result:

Proper mixing ensures uniform distribution

No sedimentation during sampling

Observed Result: **98.5%**

Conclusion: Within acceptable limit (95–105%)

- Stability Study

Method: Stored at room temperature

Result: Observed over time for: Sedimentation, Caking, Color change.

Observation: No caking, Easy redispersion, No color change.

How Much Calcium Do We Need?

Earlier, calcium requirements were assessed using calcium balance studies, which compare intake with urinary and fecal losses to estimate bone gain or loss. Studies from the 1930s–1950s showed calcium balance could be maintained with intakes from about 100 mg to several hundred mg/day, levels common in parts of Africa and Asia without bone disorders. However, intakes below ~200 mg/day were linked to rickets in children, leading to recommendations in 1974 of 400–500 mg/day for adults.

Later studies suggested higher needs (≈990 mg/day for premenopausal and 1500 mg/day for postmenopausal women), but these were influenced by methodological limitations, as balance calculations can show positive results with increased intake mathematically. More recent evidence indicates calcium balance remains stable across a wide intake range (400–1700 mg/day), with some studies showing positive balance even at ~300 mg/day in adults under 60 years.

Pharmacological Action of Calcium Carbonate Suspensions

Calcium carbonate suspension acts by supplying elemental calcium required for various body functions. In the stomach, it reacts with hydrochloric acid to form soluble calcium, which is then absorbed mainly in the small intestine through vitamin D–regulated active transport and passive diffusion. Once in the bloodstream, calcium levels are regulated by parathyroid hormone, calcitonin, and vitamin D to maintain proper balance.

Calcium plays an important role in muscle contraction, nerve transmission, blood clotting, and enzyme activity. Thus, calcium supplements help prevent or treat deficiency and support normal physiological functions.

Advantages of Calcium Supplement

1. **Easy Administration**

Liquid form is easier to swallow than tablets, making it suitable for children and elderly patients.

2. **Flexible and Accurate Dosing**

Allows precise dose adjustment based on age, weight, and condition, especially important in pediatric and geriatric use.

3. **Improved Compliance**

Flavored suspensions enhance palatability, increasing patient adherence, particularly in children.

4. **Supports Bone Health**

Helps in bone and teeth development in children, supports fetal growth in pregnancy, and prevents bone loss/osteoporosis in women.

5. **Suitable for Elderly Patients**

Beneficial in dysphagia, improves calcium absorption, reduces fracture risk, and can be formulated to minimize gastrointestinal irritation.

Disadvantages of calcium supplements

General Disadvantages (All Age Groups)

- Calcium suspension formulations are physically unstable in nature, as the dispersed particles tend to settle at the bottom over time, leading to non-uniform distribution of the drug if not handled properly.
- These suspensions require thorough shaking before each use to ensure proper mixing of the particles, and failure to do so may result in inaccurate dosing and reduced therapeutic effectiveness.
- There is a higher possibility of dose inconsistency compared to solid dosage forms, especially if the suspension is not measured carefully or evenly dispersed.

Disadvantages in Children

- The presence of sweeteners and flavoring agents in calcium suspensions, while improving taste, may contribute to increased sugar exposure and raise the risk of dental caries when used for a prolonged period.
- There is a significant possibility of dosing errors by caregivers, especially if appropriate measuring devices such as calibrated spoons or syringes are not used correctly.
- Excessive intake of calcium in children due to improper dosing may interfere with the absorption of other essential minerals, potentially leading to nutritional imbalance.

Disadvantages in Women

- High or uncontrolled intake of calcium supplements in women may increase the risk of kidney stone formation, particularly in individuals with a history of renal issues.
- Calcium supplements can interfere with the absorption of other important nutrients such as iron and zinc, which are especially critical during pregnancy and lactation.
- Some women may experience gastrointestinal discomfort, including nausea, constipation, and a feeling of heaviness, which can reduce compliance with therapy.

Disadvantages in Elderly Patients

- Elderly patients may find suspension formulations inconvenient due to the need for proper shaking, accurate measurement, and careful storage conditions, which can affect regular use.
- Since older adults are often on multiple medications, calcium suspensions may increase the risk of drug interactions by interfering with the absorption of certain drugs.
- The use of calcium supplements in this population can lead to gastrointestinal issues such as constipation, which is already a common concern among elderly individuals.

Role of Tulsi in Calcium Carbonate supplement Suspensions

Addition of *Tulsi (Ocimum sanctum)* extract to calcium carbonate suspension offers multiple advantages by improving both formulation quality and therapeutic value. It helps in masking the unpleasant chalky taste of calcium carbonate, thereby enhancing palatability and patient compliance. Tulsi also exhibits natural antimicrobial properties due to the presence of compounds like eugenol, which helps in reducing microbial growth and may decrease the need for synthetic preservatives. Furthermore, its anti-inflammatory and antioxidant activities provide added health benefits, making the formulation more effective overall. In addition, Tulsi can contribute to better stability of the suspension by supporting uniform dispersion and minimizing microbial spoilage.

The risks of too little calcium

If you don't get enough calcium, you may have issues with bone growth or weakness. Children, adolescents and adults 50 and older are at risk of having low calcium levels.

Children may not reach their full potential adult height if calcium levels are low.

Adults are at risk of bone conditions such as osteoporosis or osteomalacia due to low bone mass if they do not get enough calcium. These conditions may cause bones to break more easily or become soft.

Stability Considerations

Pharmaceutical suspensions must remain stable throughout their shelf life. Temperature, light exposure, and microbial contamination can affect stability. Preservatives and proper packaging help extend product shelf life. The suspension should be stored in tightly closed containers and protected from extreme temperatures.

Applications

Calcium supplement suspensions are widely used in pediatric and geriatric populations. They are recommended for individuals with calcium deficiency, osteoporosis risk, pregnancy-related calcium requirements, and dietary insufficiency.

Summary

The study involves the formulation and evaluation of a calcium carbonate oral suspension using HPMC as a suspending agent and Tulsi (*Ocimum sanctum*) extract as a natural additive. Calcium carbonate provides supplementation, while HPMC ensures uniform dispersion and stability. Tulsi was added to improve taste and provide antimicrobial benefits.The formulation was evaluated for parameters like pH, viscosity, sedimentation, and redispersibility, showing good stability and flow properties. Overall, the developed suspension was stable, palatable, and offered added therapeutic benefits, making it a better alternative to conventional formulations.

Conclusion

The formulation of calcium carbonate suspension is an effective method for delivering calcium upplementation. Suspensions provide advantages such as ease of administration and improved palatability. Proper selection of suspending agents and preservatives ensures stability and effectiveness of the formulation. The prepared formulation demonstrates that pharmaceutical suspensions can be successfully developed using simple laboratory techniques and commonly available excipients.

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