RESEARCH PAPER

Design And Evaluation Of A Sustained-Release Amla Formulation For Long-Term Prevention Of Scurvy

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ABSTRACT:
Long-term vitamin C deficiency is the cause of scurvy, a nutritional deficiency disorder that manifests as bleeding gums, exhaustion, poor wound healing and anemia. Amla (Emblica officinalis) has potent antioxidant qualities and is well-known natural source of ascorbic acid (vitamin C). however, frequent administration of ascorbic acid (vitamin C) is required due to its short biological half-life and poor stability. The current study intends to develop and assess a sustained release formulation of amla extract for the long-term prevention of scurvy in order to get around these restrictions. In this study, sodium alginate and Carbopol 934 were used as polymers to prepare amla extract and incorporate it into a sustained release hydrogel system. Calcium chloride was used for cross-linking in order to improve gel strength and regulate drug release. The prepared formulation was assessed for stability, invitro drug release, drug content, swelling behaviour and gel strength. Effective sustained release behaviour was indicated by the results which showed controlled and prolonged release of vitamin C over an extended period. The formulation remained stable under the specified storage conditions according to stability studies. A viable, all-natural and patient-friendly method for sustaining therapeutic vitamin C levels and averting scurvy over an extended period of time is the developed sustained release amla formulation.

Keywords: Emblica officinalis, Vitamin C, Sustained Release, Scurvy, Antioxidant
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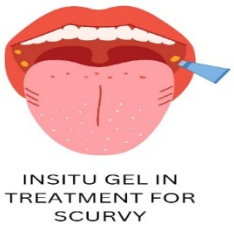
INTRODUCTION:

A prolonged lack vitamin C (ascorbic acid), a necessary water-soluble vitamin needed for collagen synthesis, antioxidant activity and healthy immune function results in scurvy, a nutrition deficiency disorder. Clinical signs of vitamin C deficiency include bleeding gums, slowed wound healing, exhaustion, anemia, joint pain and heightened vulnerability to infections. Scurvy can be avoided, but it still happens because of inadequate supplementation, malnutrition and poor dietary intake, especially in vulnerable populations. Indian gooseberry or amla (Emblica officinalis) is a well-known medicinal plant that is frequently utilized in traditional medical systems. In addition to having polyphenols, flavonoids and tannins with potent antioxidant and health-promoting qualities, it is one of the best natural sources of vitamin C. The stability and bioavailability of vitamin C are improved by these organic antioxidants. However, when given in conventional dosage forms, vitamin C requires frequent dosing due to its short biological half-life, high water solubility and chemical instability. In order to maintain therapeutic drug levels, lower the frequency doses and increase patient compliance. Sustained release drug delivery systems are made to release the active ingredient at regulated rate for a prolonged amount of time. The drawbacks of traditional vitamin C supplements can be addressed and long-term scurvy production can be obtained by adding amla extract to a sustained release formulation because hydrogel based systems with polymers like sodium alginate and Carbopol 934 are biocompatible, biodegradable and can regulate drug release to swelling and diffusion mechanisms. Drug release is extended gel strength is further increased by cross-linking with calcium ions. In order to achieve controlled delivery of vitamin C for the long-term prevention of scurvy. The current study focuses on the design and evaluation of a sustained release amla formulation using appropriate polymers. To determine the formulation efficacy as a sustained and natural vitamin C delivery system.



MATERIALS:

- Amla extract
- Carbopol 934
- Sodium alginate

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- Calcium chloride
- Sodium citrate
- Sodium Benzoate
- Glycerin

PREPARATION OF AMLA EXTRACT:

The pulp of fresh amla fruits was shade-dried after being washed and the seeds are removed. After being dried, the material was ground into powder and sieved. A Soxhlet thimble was filled with a predetermined amount of amla powder such as 250g. The Soxhlet extractor was filled with the thimble. The round-bottom flask was filled with the extraction solvent (ethanol:water,70:30). A heating mantle was used to assemble and heat the apparatus. The extraction process was continued for 6-8 hours until colorless solvents were visible in the siphon tube. By using a water bath or rotary evaporator to evaporate the solvent, the extract was concentrated. Before being used again, the concentrated extract was cooled and kept in an airtight container at 4˚C

PROCEDURE:

Weigh 1g of sodium alginate. With constant stirring, gradually add it to about 40 millilitres of distilled water. To guarantee full hydration, gently heat (below 60˚C). Until a clear, lump-free solution is achieved, keep stirring. Let the mixture cool to room temperature.

Weigh out 0.2 grams of Carbopol 934. Gently stir it around in about 10 millilitres of distilled water. Give it 30 to 45 minutes to fully hydrate. The result is a uniform and smooth dispersion.

0.25g of sodium citrate should be dissolved in about 10 ml of distilled water. To the solution above, add 0.1g of calcium chloride. Stir until the mixture turns clear. Premature gelation is avoided with this solution.

With constant stirring, gradually add the amla extract solution to the sodium alginate solution. Add the Carbopol dispersion to the mixture mentioned above, then gently stir. Stir constantly as you add 0.1g sodium benzoate and 5ml glycerin. Add the calcium chloride – sodium citrate solution gradually while stirring gently. Add distilled water to bring the final volume up to 100ml. To create a homogeneous, freely – flowing in – situ gel solution, gently stir.

EVALUATION PARAMETERS:

A. PRE-GEL / SOLUTION EVALUATION:

1. Appearance and Homogeneity:

Examine visually for uniformity, color, clarity and particulate matter.

2. pH determination:

A digital pH meter was utilised to ascertain the pH of a 1g gel that had been dispersed in 10ml of distilled water. The range is between 6.8 – 7.2 for oral use.

3. Viscosity (before gelation):

Measured at various rpms using a Brookfield viscometer.

4. Density:

A pycnometer is used to measure the mass of a known volume.

B. IN – SITU GELATION STUDIES:

1. Gelation time:

One milliliter of the formulation was added to simulated saliva (pH 6.8 with ca^{2+}); the gel formation time was recorded.

2. Gelation capacity:

Visually observed and graded (+ / ++/ +++).

3. Gel strength:

Time needed for given weight to pierce gel at a predetermined depth.

C. POST – GEL PROPERTIES:

1. Viscosity (after gelation):

After gel formation in a saliva – like fluid, viscosity was measured.

2. Spreadability:

Measured under applied weight using the glass slide method.

3. Swelling index:

The dried gel's initial weight (W_0) was noted submerged in artificial saliva and periodically reweighed (W_t).

4. Erosion study:
Gel's weight loss over time following immersion in simulated saliva fluid.

D. MUCOADHESIVE & RETENTION STRENGTH:
1. Mucoadhesive strength:
The force needed to separate the gel was measured using goat buccal mucosa.
2. Residence time:
A gel was applied to the mucosa and the detachment time was noted.

E. DRUG – RELATED EVALUATION:
1. Drug content uniformity (ascorbic acid):
Gel is dissolved, filtered and UV – Vis spectrophotometry is used analysis.
2. In – vitro drug release study:
Samples are periodically examined using a franz diffusion cell that simulates saliva fluid.
3. Release kinetics:
Data on drug releases fitted to: Zero – order, Initial order, Higuchi model, Korsmeyer – Peppas model.

F. SAFETY & BIOLOGICAL STUDIES:
1. In – vitro irritation study:
Checked for inflammation or redness on the buccal mucosa.
2. Microbial limit test:
The conventional plate count techniques for assessing the microbial load.
G. STABILITY STUDIES:
1. Accelerated stability study:
Kept at 40˚C ± 2˚C and 75% relative humidity ± 5%. Periodically assessed for: viscosity, pH and appearance content of drugs.

DISCUSSION:
The goal of the current study was to create an amla extract sustained release formulation for extended vitamin C administration in order to avoid scurvy**.** Amla's high natural vitamin C concentration and other antioxidant phytoconstituents, which improve stability and therapeutic potential led to its selection. To achieve effective extraction of both water-soluble and moderately polar elements, Soxhlet extraction was used to prepare the ethanolic extract of amla. Effective extraction was shown by the adequate percentage yield that was produced. When ethanol-water (70:30) was used as the solvent instead of just aqueous extraction, extraction efficiency was increased. Carbopol 934 improved viscosity and helped with regulated drug release, while sodium alginate created gel matrix when calcium ions were present.
The beads produced by the cross-linking technique were spherical , homogeneous and had acceptable physical properties. The formulation demonstrated regulated hydration behaviour, which is necessary for sustained drug release, according to swelling studies. The polymer matrix's capacity to absorb dissolving medium and control the diffusion of vitamin C was demonstrated by the swelling index's gradual increase. Amla extract was evenly distributed throughout the formulation, according to drug content analysis, suggesting adequate mixing and little drug loss during processing. A sustained release pattern over a long time span was shown in the in-vitro drug release research, indicating that the polymer combination successfully regulated vitamin C release. According to the release kinetics analysis and the Higuchi model, the mechanism was diffusion-controlled release.

REPORT:
Stability studies performed under accelerated conditions demonstrated no significant alterations in physical appearance, drug content or release profile thereby affirming formulation stability. In general, the developed sustained release amla formulation showed good signs for long-term vitamin C supplementation. This method may help patients follow their treatment plans and offer a natural, low-cost way to prevent scurvy.

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