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Formulation and development of catechin based nanogel for gingivitis

MA Khambalkar*[1], PY Patil[2], MN Kapashikar[3], HD Jedage[4], VR Sangale[5].

*[1]Research Scholar, Department of Pharmaceutics Mauli College of Pharmacy, Tondar, Udgir (MH) 413517

[2]Research Guide, Department of Pharmaceutics Mauli College of Pharmacy, Tondar, Udgir (MH) 413517

[3]Department of Pharmaceutics Rajarambapu College of Pharmacy, Kasegaon, Dist. Sangli (MH) 415404

[4]Principal & Professor, Mauli College of Pharmacy, Tondar, Udgir (MH) 413517

[5]Department of Pharmaceutics, Mauli College of Pharmacy, Tondar, Udgir (MH) 413517

Abstract

This thesis focuses on the formulation and development of a novel catechin-based nanogel for the targeted delivery of catechin hydrate to gingival tissues, aiming to address the limitations of conventional therapies in gingivitis management. Nanogel formulation was formulated using Carbopol 934 and Poloxamer 407 polymers, was meticulously designed to encapsulate catechin hydrate efficiently and ensure sustained release kinetics in the oral cavity. The Nanogel was evaluated for its Homogeneity, pH, Spreadability, Particle size & Zeta potential, Viscosity, In- vitro release study and stability profile of the catechin-based nanogel formulation through a series of in vitro experiments and analyses. The In-vitro release of Catechin hydrate Nanogel was observed in the range of 83.746%- 94.846%. Initial burst release studies revealed rapid onset of therapeutic action, followed by sustained release kinetics, maintaining therapeutic levels ofcatechin hydrate over an extended period. Moreover, the stability study conducted over a three- month period confirmed the robustness and integrity of the nanogel formulation. The developed formulation exhibited favorable properties, including uniform particle size distribution, mucoadhesive properties, and compatibility with oral tissues.

Keyword: Gingivitis, Catechin, Nanogel.

INTRODUCTION

Gingivitis, stemming from the inflammation of gingival tissues, serves as the initial stage of periodontal diseases. Primarily caused by the accumulation of bacterial plaque along the gumline, it manifests as redness, swelling, and bleeding of the gums upon provocation. Microbial biofilms, chiefly composed of bacteria such as Porphyromonas gingivalis and Prevotella intermedia, trigger an immune response, leading to the release of inflammatory mediators like cytokines and prostaglandins. This inflammatory cascade initiates gingival tissue damage and vascular alterations, marking the onset of gingivitis. Oral bacteria, predominantly those in plaque, accumulate on tooth surfaces, especially at the gumline. These bacteria, including Porphyromonas gingivalis, Prevotella intermedia, and others, form biofilms within dental plaque. Bacterial plaque triggers the host immune system. This leads to the release of inflammatory mediators, including cytokines (e.g., interleukin-1β, tumor necrosis factor-α) and prostaglandins.

Without intervention, gingivitis can advance to periodontitis, a more severe and irreversible form of periodontal disease. Periodontitis involves the destruction of the supporting structures of the teeth, including the periodontal ligament and alveolar bone. This progression occurs due to the continued inflammatory response, leading to the formation of periodontal pockets, bacterial colonization, and subsequent tissue and bone loss. The ongoing inflammation and immune response cause destruction of the periodontal ligament that attaches the tooth to the bone. Concurrently, there is resorption (loss) of the alveolar bone, the bone that holds the tooth socket in place. As a consequence, the tooth loses its anchorage and becomes mobile. Visible signs include deeper pockets between the gums and teeth, gum recession, increased tooth mobility, and sometimes pus formation. Patients may experience pain or discomfort, especially during chewing, due to the compromised stability of the affected teeth.

Gingivitis represents a prevalent oral health issue globally. Epidemiological studies highlight its widespread occurrence, with a substantial percentage of the population affected by varying degrees of gingival inflammation. Factors such as inadequate oral hygiene, genetic predisposition, systemic conditions, and lifestyle habits contribute to the prevalence and severity of gingivitis across different demographics. Gingivitis is a highly prevalent oral health condition globally, affecting a significant portion of the population irrespective of age, gender, or geographic location. Epidemiological studies indicate varying degrees of gingival inflammation, with estimates suggesting a substantial proportion of individuals experiencing mild to moderate forms of gingivitis. Poor Oral Hygiene Inadequate or inconsistent oral hygiene practices, including irregular brushing and inadequate plaque removal, significantly contribute to the development of gingivitis.

Bacterial Resistance Prolonged use of antimicrobial agents in mouth rinses or topical applications might lead to bacterial resistance, reducing their effectiveness in controlling plaque and gingival inflammation Smoking and Diet Tobacco use and poor dietary habits can exacerbate gingival inflammation, making management challenging. Encouraging behavioral

changes, such as smoking cessation or dietary modifications, can be demanding. Treatment Scope Some treatment modalities might primarily target symptoms without addressing the root cause of gingival inflammation, necessitating ongoing maintenance and management.

Catechins possess strong antioxidant capabilities, protecting cells and tissues from oxidative stress by neutralizing free radicals and reactive oxygen species (ROS). They demonstrate anti- inflammatory properties by modulating inflammatory pathways and reducing the production of pro-inflammatory mediators, potentially beneficial in managing inflammatory conditions like gingivitis. Catechins exhibit antimicrobial effects against various pathogens, including bacteria, viruses, and fungi. Specifically, EGCG has shown efficacy against oral bacteria implicated in periodontal diseases.

Catechins have shown efficacy in inhibiting the growth and proliferation of various oral pathogens, including

Streptococcus mutans, Porphyromonas gingivalis, and Prevotella intermedia, which are implicated in gingivitis and periodontitis. Catechins interfere with the ability of bacteria to adhere to oral surfaces and epithelial cells, thus reducing their ability to colonize and initiate infections in the oral cavity. They may disrupt the interaction between bacterial adhesins and host cell receptors, hindering bacterial attachment to oral tissues. Catechins exhibit anti-inflammatory properties by modulating the production of inflammatory cytokines (e.g., interleukins, tumor necrosis factor), thus mitigating the inflammatory response ingingival tissues.[1,2,3]

1. Materials and Methods

1.1 Drug

Catechin Hydrate was purchased from Tokyo Chemical Industry (India) Pvt. Ltd. Hyderabad.

1.2 Construction of calibration curve for Catechin Hydrate

General The solutions were prepared by weighing suitable quantity of Catechin Hydrate on aluminum foil using pre-calibrated analytical weighing balance. The weighed quantity was transferred to a volumetric flask and solubilized using analytical grade Methanol. Prior toanalysis, both cuvettes were washed with distilled water twice and rinsed with methanol twice to ensure complete cleaning. Then cuvettes were again rinsed with Methanol. During UV analysis, both cuvettes were filled with Methanol and reading was adjusted using Auto Zero button. Then, subsequent absorbance measurements were carried out.[16,17]

1.3 Preparation of Stock Solution

10 mg of Catechin hydrate was exactly weighed using pre-calibrated analytical balance, transferred in 10 mL volumetric flask and dissolved in sufficient purified water using sonication. It produced a solution of 1mg/mL strength (Stock-1). From the stock 1 take 1 ml and dilute to 10

ml with purified water to produce 100 µg/ml (Stock-2) solution. The Stock-1 containing flask was covered with foil and sealed with paraffin film to avoid degradation and loss due toevaporation.

1.4 Determination of Analytical Wavelength (λmax)

Sufficient volume of Stock-2 was scanned under UV region of 400-200 nm using purified water as blank. The wavelength, at which there was maximum absorption, was selected as wavelength for analysis.

1.5 Preparation of Standard curve

A five point standard curve of Catechin hydrate was prepared using different concentrations of drug from Stock-1 solution. The concentration range selected was from 2µg/mL to 12µg/mL. Concentrations of 2 µg/mL, 4 µg/mL, 6µg/mL, 8 µg/mL, and 10µg/mL and 12µg/mL were prepared by appropriate dilutions of Stock-1 solution.

1.6 Drug polymer compatibility study

To investigate any possible interactions between the Catechin hydrate and the used excipients, infrared spectroscopy was adopted. The IR spectrum of pure drug, polymer as well as physical mixture of drug and polymer was taken, interpreted and compared with each other. The IR spectra was carried out using Bruker (Alpha) IR spectrophotometer. The samples were prepared as potassium bromide discs compressed under a pressure of 6 tons. The scanning range was over 4000-400 cm-1.[18]

1.7 Pre-formulation studies

A) Description: The sample's appearance, colour, and odour were assessed visually.

B) Melting point: The capillary tube method was used to evaluate the melting points ofCatechin hydrate.

C) Solubility:

Catechin hydrate was studied for solubility in both water and organic solvents. Three test tubes containing 10 mg of the Catechin hydrate were filled with the necessary amount of reputable solvent. Shaking the test tubes to check for solution clarity was done.

2. Formulation development of Catechin based nano-gel for Gingivitis

The nanogel of Catechin hydrate as prepared using carbapol 934, Poloxamer 407, propylene glycol, triethanolamine, methyl paraben, propyl paraben and distilled water in quantity sufficient to prepare nanogel.[19,20]

Batch Code	Drug and excipients						
	Drug (Catechin hydrate) (mg)	Carbapol 934 (mg)	Poloxamer 407 (mg)	Triethanol amine (mg)	Methyl paraben (mg)	Propyl paraben (mg)	Water (ml)
B1	10	350	20	2	8	4	20
B2	10	400	40	2	8	4	20
B3	10	500	60	2	8	4	20
B4	10	500	20	2	8	4	20
B5	10	400	60	2	8	4	20
B6	10	350	40	2	8	4	20

2.1 Method of preparation of Catechin hydrate nanogel

The water was taken and Poloxamer 407 was slowly added to form a Poloxamer solution. The Catechin hydrate was accurately weighed and added to the Poloxamer solution. Carbopol 934 has been submerged in water. After swelling, the carbopol has been kept on a magnetic stirrer forstirring. The Poloxamer solution containing Catechin hydrate was slowly added to the Carbopol 934 solution to form a gel The preservatives like methyl paraben and propyl paraben was added in to the final gel Lastly, Triethanolamine is added for pH adjustment.[23,24]

3. Evaluation of Catechin hydrate nano gel

4.1. Homogeneity

Visual checks were made to ensure that each generated formulation was homogeneous after the Nano-gel had been added to the container. We looked at the homogeneity of the formulations to see if there were any aggregates and whether they were visible.

4.2. Measurement of pH of Catechin hydrate Nanogel

On an Elico (LI-120) pH metre, the pH of the Nanogel was determined. One gram of nanogel was dissolved in 100 ml of filtered water, and the mixture was left undisturbed for two hours. Calculating the average of the three measurements of each formulation's pH was done.

4.3. Spreadability of Nanogel

A circle with a 1 cm diameter was created on a glass plate, and 0.5 g of gel was added to it. The glass plate was

then placed over another plate to determine the spreadability. A 50 g weight was allowed to rest on the upper glass plate for five minutes. Spreadability was measured by following formula

S = ML/T

Where,
M is the weight fastened to the upper slideL is the length of the glass slides

T is the time required to separate the slides.

4.4. Particle size & Zeta potential determination of Nanogel

Zetasizer (Malvern Zetasizer) measures the nanogel preparation's zeta potential and particle by placing the formulation in a transparent, single-use zeta cell and measuring the outcome. Using methanol to clean the cuvettes, the sample is added before doing the experiment.

4.5. Viscosity Measurement

A Brookfield viscometer (Model LMDV 60) was used to measure the nanogel viscosity. The 50g of nanogel that had been precisely measured was put to the 50 ml glass beaker. Spindle number4 was chosen, and it is submerged in the nanogel. The viscometer was run at 10 rpm until the reading stabilised and was recorded in Pas.

4.6. Moisture Absorbing Test

In this test, a desiccator is filled with one gram of Nanogel. In addition, distilled water-filled beakers are positioned adjacent to the nanogel in the same desiccator. The nanogel should then be weighed and checked 24 hours later. A nanogel formulation's weight would increase if it wereto absorb any liquid.

4.7. Drug content analysis

Drug contents of formulations were determined in triplicate by using double beam UV visible spectrophotometer (Lasany Microprocessor UV-VIS Double Beam spectrophotometer Model: (LI2702). One milliliter of formulation was taken in capacity of 10 ml volumetric flask, diluted with 10 ml of double distilled water. Finally, the absorbance of prepared solution was measured at 278 nm by using UV visible spectrophotometer.

4.8. Gel strength determination

The strength of the nanogel was measured as the time in seconds required for a weight to pass through it. A 5 gram sample was delivered to each of the successful batches. 3.5 gm of weight were placed to the nanogel's surface. The time it takes for the weight to stab the gel for 0.5 cm.

4.9. In-vitro release study

The drug release studies were conducted using Franz diffusion cells, which had an effective diffusion area of 3.14 cm 2 and a cell volume of 16.5 mL. A thin (1 g) layer of Nanogel was placed to the surface of the Cellophane membrane. A cellophane membrane was clamped in the diffusion cell's donor and receptor chambers. Phosphate buffer solution (pH 6.8) was newly

prepared and poured into the receptor chamber. Using a magnetic stirrer, the receptor chamber was stirred. Samples were collected at the necessary intervals. Samples were analysed for drug content using a UV visible spectrophotometer at max (nm) following the necessary dilutions. The drug was then entirely replaced with new buffer after computing the overall amount of drug released for each suitable time interval as a function of time.

4.10. Stability study of Catechin hydrate Nanogel

Stability Study The stability of both closed and open containers was tested. In this experiment, nanogel spent three months at ambient temperature.[21,24]

4. Results & Discussion

4.1 Determination of Analytical Wavelength (λmax)

The Maximum wavelength detection of Catechin hydrate were carried out. The maxium wavelength was found to be 278nm by using UV visible spectrophotometer. The calibration curve of the Catechin hydrate was developed by using these maxima as fixed wavelength.

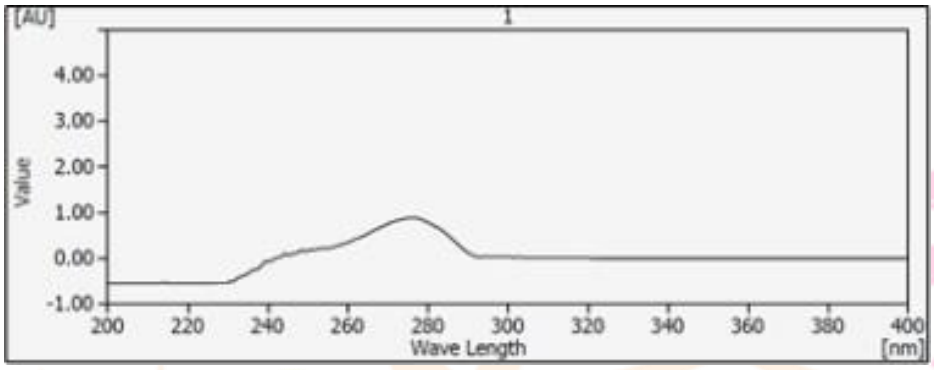

Figure 1: Maximum wavelength determination of Catechin hydrate

4.2 Development of calibration curve for Catechin Hydrate

The calibration curve of Catechin hydrate was performed and graph plotted concentration vs. absorbance. The absorbance values of different concentration were noted. The regression equation was found to be y = 0.0983x-0.0015, with R2 value of 0.9993. The graph was found to be linear.

Sr No.	Concentration (ppm)	Absorbance
1.	2	0.184
2.	4	0.395
3.	6	0.597
4.	8	0.787
5.	10	0.991
6.	12	1.164

Table 2: Concentration range and respective absorbance of Catechin hydrate

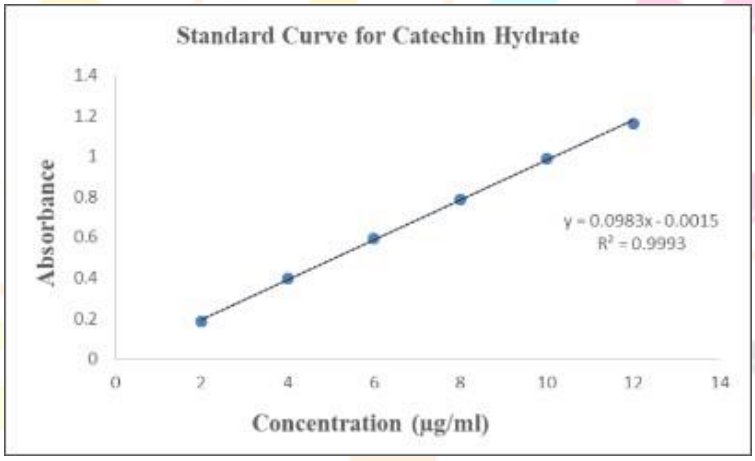

Figure 2: Calibration curve for Catechin hydrate

4.3 Drug polymer compatibility study

The compatibility study of Catechin hydrate and Carbapol 934, Poloxamer 407 and physicalmixture were carried out using Infrared spectrophotometer.

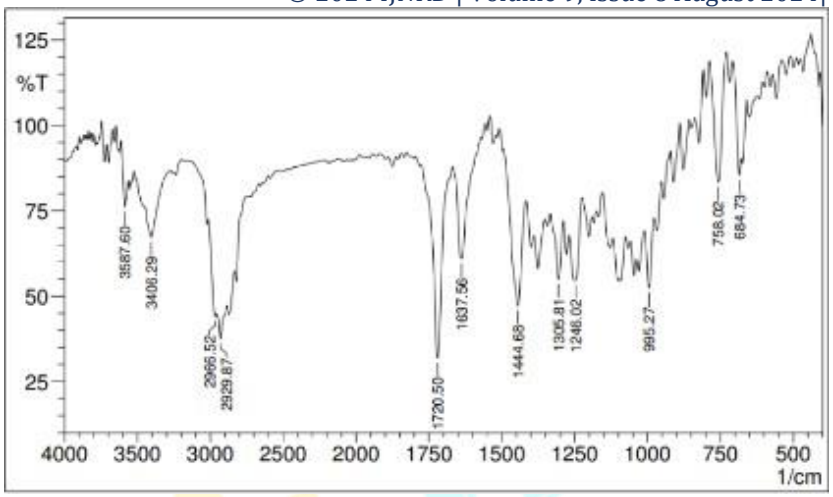

Figure 3: FTIR Spectra of Catechin hydrate

Functional Group	Observed frequencies (in cm^{-1})
Hydroxyl (OH)	3406.29
C-H stretching	2966.52,2929.87
C=O Stretch (Ketone)	1720.50
C=C Stretch (Aromatic)	1637.56

Table 3: IR absorbance bands of pure Catechin hydrate

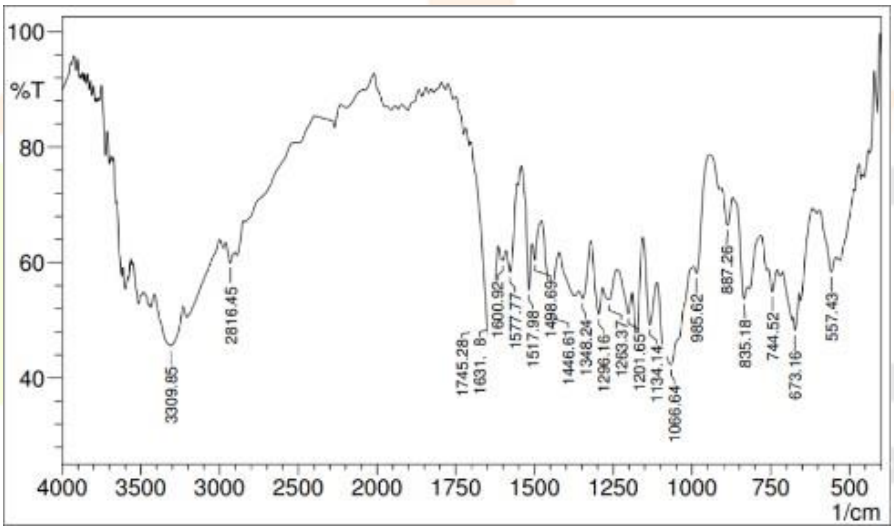

Figure 4: FTIR Spectra of Carbapol 934

Functional Group	Observed frequencies (in cm^{-1})
O-H Stretch (Hydroxyl)	3309.85
C-H Stretch (Aliphatic)	2816.45
C=O Stretch (Carbonyl)	1745.28
C-O Stretch (Ester)	1134.14, 1201.65

Table 4: IR absorbance bands of pure Carbapol 934

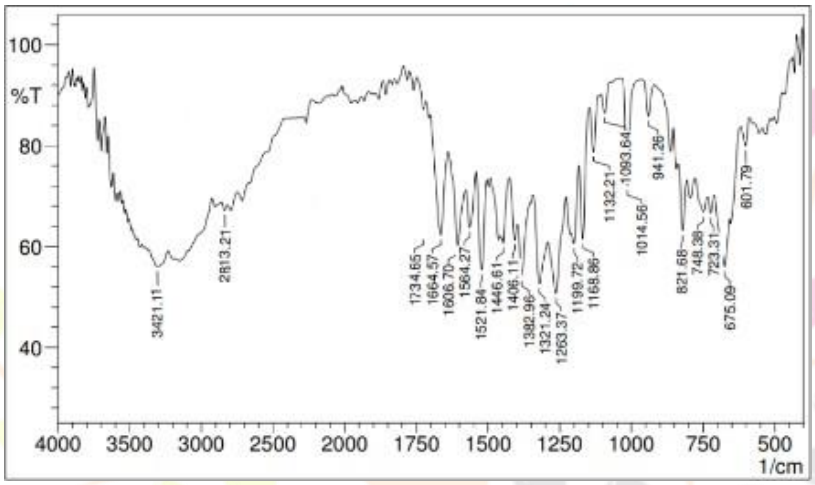

Figure 5: FTIR Spectra of Poloxamer 407

Functional Group	Observed frequencies (in cm^{-1})
O-H Stretch (Hydroxyl)	3421.11
C-H Stretch (Aliphatic)	2813.21
C=O Stretch (Carbonyl)	1734.65
C-O Stretch (Ether)	1132.21

Table 5: IR absorbance bands of pure Poloxamer 407

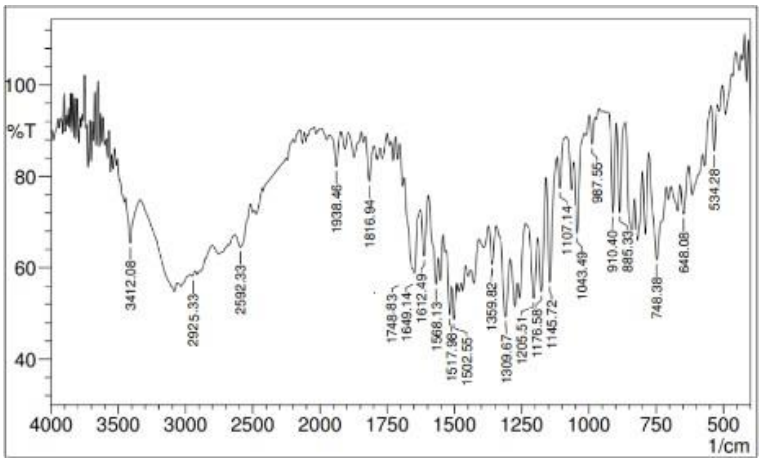

Figure 6: FTIR Spectra of Physical mixture

Functional Group	Observed frequencies (in cm^{-1})
O-H Stretch (Hydroxyl)	3412.08
C-H Stretch (Aliphatic)	2925.33
C=O Stretch (Carbonyl)	1748.83
C-O Stretch (Ether/Carboxyl)	1145.72, 1205.51
C=C Stretch (Aromatic)	1612.49,1649.14

Table 6: IR absorbance bands of physical mixture

FTIR spectra of pure Catechin hydrate and excipients revealed that functional group frequencies of Catechin hydrate have been found similal. The IR 3412.08 cm-1 is assigned to-OH stretch Aromatic and IR 2925.33 cm-1 is assigned to C-H Stretch Aliphatic, suggesting that the cubic form of Catechin hydrate. The main characteristic peak of Catechin hydrate was the Alkene Stretch (Aromatic) which was appeared at 1612.49, 1649.14 cm-1.

4.4 Pre-formulation studies of Catechin hydrate Nanogel

In pre-formulation studies the organoleptic properties of Nanogel were observed. The table includes the properties of trial batch.

Figure 7: Trial batch of Catechin hydrate Nonogel

Formulation	Physical appearance				
	Color	Texture	Homogeneity	Melting Point	Solubility
Trial batch	Brownish	Smooth	Homogenous	~200 °C	Soluble in methanol, ethanol, also soluble in water

Table 7: Physical appearance analysis of Catechin hydrate Nanogel

4.5 Formulation development of Catechin based nano-gel for Gingivitis

On the basis of trail batch and understanding of preliminary properties of Catechin hydrate nanogel six batch were formulated by changing the concentration of Carbapol 934 and Poloxamer 407 to get the best formulation among six developed formulation of nanogel. The effect of change in concentration of these both polymer will ultimately change the results of the individual batch. To get the best formulation among the six the batches were evaluated for its performance.

5. Evaluation of Catechin hydrate nano gel

5.1 Determination of Homogeneity of Naogel

Homogeneity refers to the uniform distribution of components within the nanogel formulation. A homogeneous nanogel ensures consistent delivery of Catechin hydrate and enhances efficacy. Homogeneity assess homogeneity visually and results indicating good homogeneity would show uniform dispersion of catechin hydrate particles throughout the nanogel matrix without any signsof aggregation or phase separation in all the batches.

Figure 8: All six different formulation batches of Catechin hydrate Nanogel for Gingivitis

5.2 Determination of pH of Nanogel

The pH of the Catechin hydrate nanogel formulation is crucial as it can affect its stability, compatibility with oral tissues, and the release of active ingredients. Catechin hydrate nanogel for gingivitis should ideally have a pH within the physiological range of the oral cavity (approximately 5.5 to 7.5). All the formulation batches showing a pH within this range indicate that the nanogel is unlikely to cause irritation or discomfort upon application and is compatible with oral tissues.

Formulation code	Evaluation Parameters		
	Homogeneity	pH	Spreadability (gm.Cm/sec)
B1	Homogenous	5.86	5.64
B2	Homogenous	6.31	6.37
B3	Homogenous	6.47	7.26
B4	Homogenous	6.53	7.13
B5	Homogenous	5.96	6.68
B6	Homogenous	6.42	5.85

Table 8: Showing the Homogeneity, pH and Spreadability of Catechin hydrate Nanogel

5.3 Determination of Spreadability of Nanogel

Spreadability refers to the ability of the nanogel formulation to spread evenly over the gingival tissues upon application. Good spreadability ensures uniform coverage of the affected area and facilitates the absorption of active ingredients. Spreadability assess by using qualitative methods (visual observation) or quantitative techniques (such as spreadability index measurement). Results indicating good spreadability would show uniform and easy spreading of the nanogel over the gingival tissues without leaving a sticky or greasy residue. The Spreadability was measured in gm.Cm/sec. batch 3 (B3) showing the more Spreadability which revealed that B3 was spread evenly.

5.4 Particle size & Zeta potential determination of Nanogel

Particle size analysis provides information about the size distribution of particles within the nanogel. It helps in understanding the dispersion characteristics, stability, and potential foraggregation.

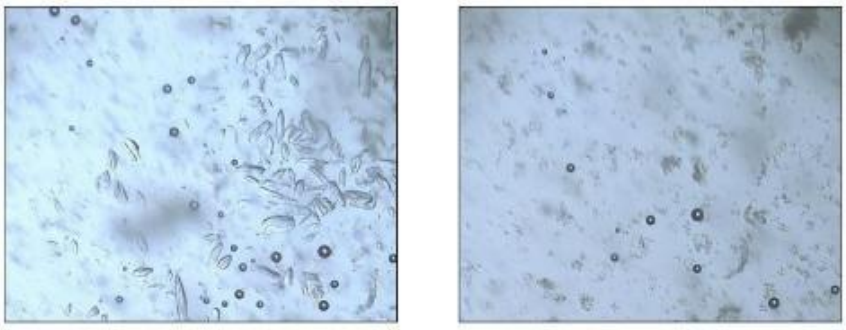

Figure 9 : Microscopic photograph of catechin hydrate Nanogel

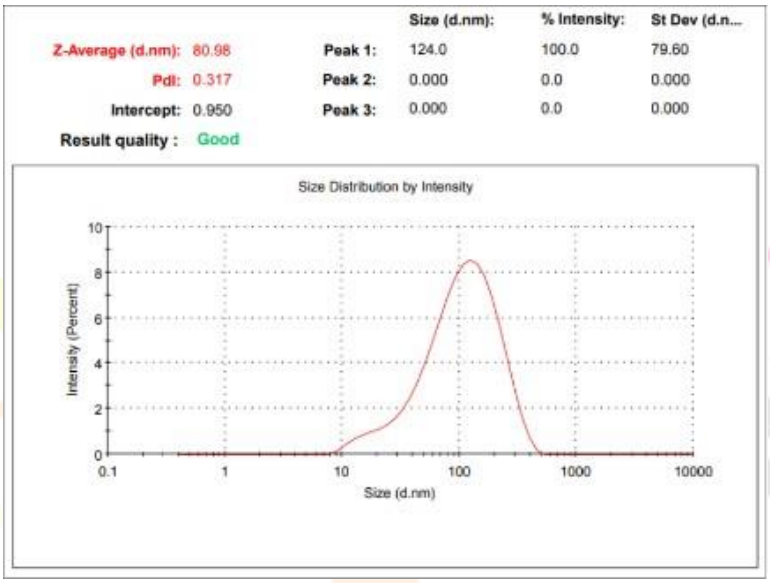

Figure 10: Particle size determination of catechin hydrate Nanogel

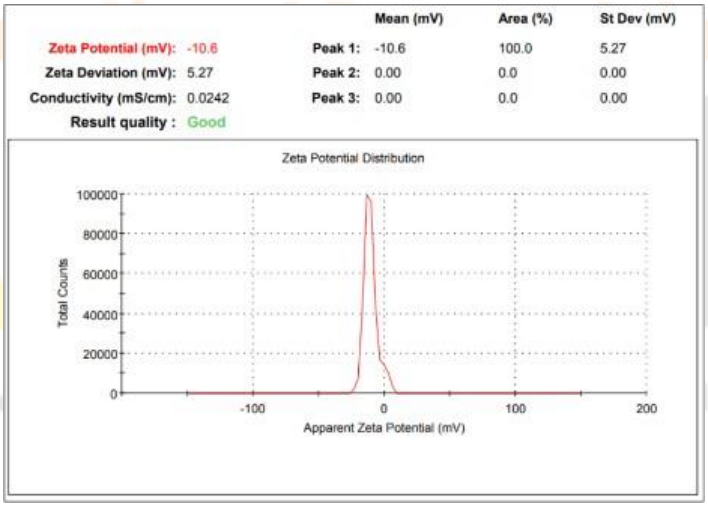

Figure 11: Zeta potential determination of catechin hydrate Nanogel

The particle size of formulation batch 3 (B3) was found to be 80.98 nm which is too less revealed that the Catechin hydrate was present in Nano form which ultimately results in the goodabsorption and dissolution release. The zeta potential of B3 was found to be -10.6 which was showing the good potential. The concentration of two polymer will affect the particle size and zeta potential. Optimization of these parameters is essential to achieve desired particle characteristics and ensure the stability and efficacy of the nanogel for gingivitis.

5.5 Viscosity Measurement

The viscosity of the catechin hydrate nanogel is a crucial parameter that influences its spreadability, stability, and ultimately its effectiveness in treating gingivitis. Viscosity refers to the resistance of a fluid or gel to flow, and it plays a significant role in determining the gel's consistency and ability to adhere to the gingival tissues.

Formulation Code	Viscosity (CPS)
B1	2864.24
B2	2567.61
B3	2245.14
B4	2396.10
B5	2847.84
B6	2965.62

Table 9: Showing the Viscosity of Catechin hydrate Nanogel

The viscosity of the nanogel can be adjusted by modifying the concentration of thickening agentssuch as Carbopol 934 or Poloxamer 407. Balancing the viscosity is crucial to achieve the desired gel consistency that is easy to apply while ensuring adequate adhesion and retention on the gingival tissues. Formulation Batch 3 (B3) showing the less viscosity among the all which showing the good spreadability, stability.

5.6 Moisture Absorbing Test

The formulation batches F1 to F6 pass the test since there are no weight changes when the nanogel is placed next to a beaker that is filled with water in the desiccator.

5.7 Drug content analysis

Determining the drug content in a nanogel formulation is crucial for ensuring the accurate dosing of the Catechin hydrate and assessing the quality and consistency of the formulation.

Formulation Code	Drug Content (Catechin hydrate content) (%)
B1	88.64
B2	86.37
B3	96.51
B4	91.58
B5	90.84
B6	88.26

Table 10: Showing the Drug content of Catechin hydrate Nanogel

The Batch 3 formulation (B3) shows the more percent drug content in the formulation due to the higher concentration of Polaxamer 407. The B3 shows 96.51% drug content in the formulation.

5.8 Gel strength determination

Gel strength determination is an important parameter to assess the mechanical properties and consistency of nanogel formulations. Gel strength reflects the ability of the gel to resist deformation under applied forces.

Formulation Code	Nanogel strength (Second)
B1	18
B2	23
B3	25
B4	28
B5	31
B6	24

Table 11: Showing the Nanogel strength of all formulations

The batch 3 was showing the gel strength of 25 sec which was the best strength of nanogel found.

5.9 In-vitro dissolution release study

This dissolution profile is designed to mimic the release pattern of catechin hydrate from a nanogel formulation in simulated physiological conditions relevant to oral cavity. It allows for both immediate drug release for rapid therapeutic action and sustained release for prolonged efficacy, essential for managing gingivitis effectively. Nanogel of Catechin hydrate containing

Carbopol 934 and Poloxamer 407 involves considering the release characteristics of these polymers and their interaction with the encapsulated drug, catechin hydrate. The initial burst release phenomenon observed in dissolution studies of nanogel formulations represents a rapid and substantial release of the encapsulated drug within the first few minutes of testing. The initial burst release phenomenon observed in dissolution studies of nanogel formulations represents a

addition to swelling, surface erosion of the nanogel matrix may occur, leading to the immediate release of drug molecules located near the surface of the nanogel particles.

Sustained release characteristics refer to the ability of a drug delivery system, such as a nanogel formulation, to release the encapsulated drug over an extended period while maintaining therapeutic levels in the target tissue or bloodstream. In nanogel formulations, the drug is dispersed within a polymer matrix. Sustained release occurs as the drug diffuses through the matrix at a controlled rate, influenced by factors such as polymer composition, crosslinking density, and drug-polymer interactions.

In Formulation batch 3 (B3) if we observed initially burst release of Catechin hydrate followed by the sustained release of same. The percent dissolution release of Catechin hydrate was observed in range of 83.74 % to 94.84%. All data of release study was given in table

Figure 12: In-vitro Dissolution study diffusion cell

Time (Min)	Percent Drug Release (%)					
	B1	B2	B3	B4	B5	B6
0	0.000	0.000	0.000	0.000	0.000	0.000
5	15.341	17.610	20.530	17.194	11.470	10.386
15	26.864	28.743	33.794	28.175	22.674	21.846
30	34.687	37.146	41.527	39.847	34.723	31.584
60	48.627	43.842	54.967	49.861	42.518	40.963
120	62.843	60.841	74.186	70.548	63.748	61.746
240	76.842	73.864	87.468	84.843	76.384	72.467
360	86.681	85.674	94.846	91.587	84.791	83.746

Table 12: Percent release profile of Catechin hydrate Nanogel for Gingivitis

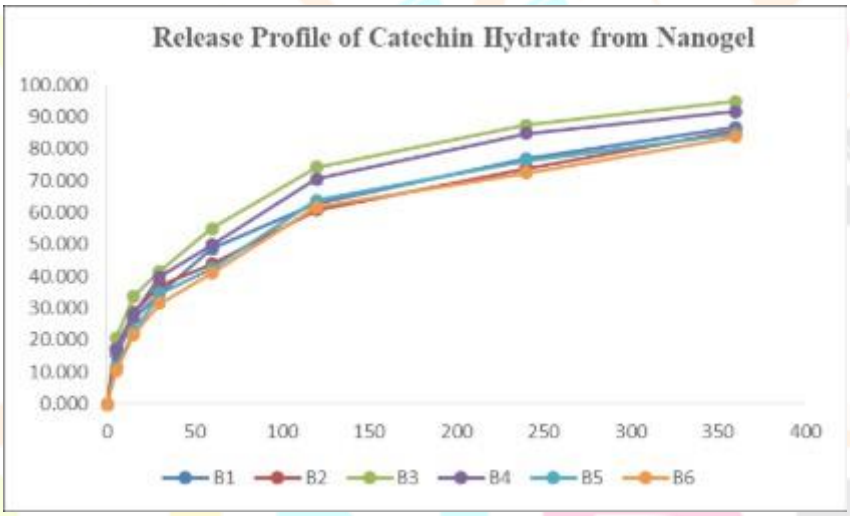

Figure 13: Percent release profile of Catechin hydrate Nanogel

5.10 Stability study of Catechin hydrate Nanogel

Stability study of Catechin hydrate Nanogel was carried out of formulation batch 3 (B3) at different temperature and humidity condition. From the study it was observed that the nanogel was stable for the period of three months. The parameters like pH, color, texture and viscosity was evaluated for 1 month and three months. There was no change observed in this parameter. The results are summerised in table.

Temperature and humidity	Parameter	Stability data for 1 month	Stability data for 3 month
30 ± 2°C /65 ± 5% RH	pH	6.47	6.38
	Color	Brownish	Brownish
	Texture	Smooth	Smooth
	Viscosity (CPS)	2168.58	2234.24
40 ± 2°C /75 ± 5% RH	pH	6.53	6.48
	Colour	Brownish	Brownish
	Texture	Smooth	Smooth
	Viscosity (CPS)	2364.47	2285.67

Table 13: Stability study data of Catechin hydrate Nanogel of B3

6. Conclusion

In conclusion, the formulation and development of a catechin-based nanogel for gingivitis present a promising avenue for the management of this prevalent oral health condition. Our study demonstrated the feasibility of incorporating catechin hydrate into a nanogel matrix composed of Carbopol 934 and Poloxamer 407, providing a stable and sustained drug delivery system for targeted application in the oral cavity. The nanogel exhibited favorable characteristics, including uniform particle size distribution, controlled release kinetics, and mucoadhesive properties, essential for efficient drug delivery to gingival tissues. The dissolution profile revealed an initial burst release of catechin hydrate, ensuring rapid onset of therapeutic action against gingival inflammation sustained release phase, maintaining therapeutic levels of the drug over an extended period. Formulation batch 3 (B3) was showing the highest drug release up to 94.84 %in 360 min (4hrs). This release profile aligns well with the requirements for effective management of gingivitis, providing both immediate relief of symptoms and prolonged protection against disease progression. The stability study conducted over a three-month period confirmed the robustness and integrity of the catechin-based nanogel formulation, with no significant changes observed in physical appearance, chemical composition, or rheological properties.

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