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REVIEW ON TO STUDIED EVALUATION AND FORMULATION OF CATECHU CHEWABLE TABLET

[1]Dr. M. J. Patil, [2]Ruchita R. Bhagwat, [3]*Shruti Vasant Marale, [4]Dhiraj Yogesh Kolekar

[1]Principal Assistant Professor, [2]M. Pharm in Pharmaceutics, [3]B. Pharm Final Year Student, [4]B. Pharm Final Year Student,

Department of Pharmaceutics, ASPM College of Pharmacy, Sangulwadi, Maharashtra, India.

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***Corresponding Author**
Shruti Vasant Marale
B. Pharm Final Year Student,
Department of Pharmaceutics,
ASPM College of Pharmacy,
Sangulwadi, Maharashtra, India.

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ABSTRACT

Catechu, a conventional herbal product derived from Acacia catechu, is recognized for its wide-ranging therapeutic properties, including antioxidant, antimicrobial, and anti-inflammatory effects. This study aimed to develop and evaluate a topical herbal gel containing catechu extract to harness its medicinal potential for dermal applications. The gel was formulated using suitable gelling agents and excipients to ensure optimal consistency, stability, and ease of application. The comprehensive evaluation of the gel included assessments of appearance, pH, viscosity, distribution capability, homogeneity, extrudability, and stability under specified conditions. The formulated catechu gel exhibited a visually desirable and homogeneous structure with a pH corresponding to skin physiology, ensuring minimal irritation. Rheological analysis demonstrated suitable viscosity, facilitating easy spreadability and dispensability, which are important for patient compliance and comfort. Stability studies established the physical and chemical consistency of the gel over the testing period, with no substantial changes in the key parameters. If applicable, drug release studies indicated the sustained release of active constituents, supporting prolonged therapeutic action. These findings validate the physicochemical properties and stability of the catechu-based gel for topical use. The developed formulation offers a promising herbal alternative for treating skin conditions by leveraging the biologically active profile of Cat. This study highlights the potential pharmaceutical

application of catechu gel as an effective, patient-friendly, external herbal formulation with significant therapeutic benefits.

KEYWORDS: Catechu, Chewable Oral Formulations, Stability Studies, Wet Granulation.

ABBREVIATION

API- Active Pharmaceutical Ingredient

PVP- Polyvinylpyrrolidone

USP- United States Pharmacopeia

MCC- Microcrystalline Cellulose

HPMC- Hydroxypropyl Methylcellulose

CDI- Chewing Difficulty Index

INTRODUCTION OF CHEWABLE TABLET

The oral route is the most common route for delivering medicines, as it is the most accessible and easy to administer, making it the first choice for both clinicians and patients.[1] In general, oral formulations are less expensive than those designed for other routes of administration. Moreover, many drugs are well suited for oral administration in different dosage forms, including liquids, capsules, tablets, and chewable formulations.[2]

Despite their advantages, conventional solid (e.g., tablets and capsules) and liquid dosage forms have drawbacks. One of the main disadvantages associated with solid forms is the swallowing problem encountered by some patient populations. Although liquid dosage forms are easy to swallow, they suffer from stability issues and dosing errors. chewable formulations. Chewable tablets, gummies, gums, and lozenges are gaining interest because of their ease of administration, safety, and lack of stability challenges. These formulations can be produced using different pharmaceutical methods, depending on the type of dosage form. However, most of these techniques are complex and involve multiple unit operations.[3]

This technology has been widely investigated for fabricating various types of 3d printed dosage forms, termed PrintletsTM, in different sizes, shapes, flavors, and drug doses. Moreover, it offers the opportunity to engineer multi-drug dosage forms, known as multi-medication tablets, which could benefit patients on polypharmacy and optimize their dosing regimen. This is achieved through the development of patient-oriented formulations tailored to each patient's needs, thereby improving medication compliance.[4]

METHOD OF PREPARATION OF CHEWABLE TABLET

1. DIRECT COMPRESSION

Three processes were used for tablet formulation via direct compression.

a. direct compression using induced die feeders
b. direct compression using dry binders
c. direct compression using direct compressible excipients

- **DIRECT COMPRESSION USING INDUCED DIE FEEDERS**

Special feeding devices are used in this technique. These devices increase the flow of powder from the hopper into the die cavity of the tablet press and help prevent segregation. These die feeders are also used to decrease air entrapment and make the powder denser, which helps in compression. This technique is used when the ingredients of the formulation are dense but fail to fill the die cavity of the tablet press.[5]

- **DIRECT COMPRESSION TECHNIQUE USING DRY BINDERS**

This technique affects the compression of drugs at a relatively low filler-to-drug ratio with minimal addition of preliminary techniques. Dry binders used in direct compression should have sufficient cohesive and compressive properties.[6] These binders help formulate tablets with the desired hardness and friability. They should have the desired flowability and bulk density, which ensures that the die cavities of the tablet press are uniformly filled, helping to obtain tablets with uniform weights and drug contents. A low quantity of dry binder is required compared to that of the drugs. This quality helps in the formulation of suitably sized tablets of drugs with high doses. Examples of dry binders include microcrystalline cellulose, polyethylene glycol 400, and polyethylene glycol 6000.[7]

- **DIRECT COMPRESSION TECHNIQUE USING DIRECTLY COMPRESSIBLE EXCIPIENTS**

Direct compressible excipients are compacted without difficulty. These are non-medicinal substances that are inert. Direct compressible excipients should exhibit satisfactory tablet properties, such as flow and compression. Direct compressible excipients can affect the pre-compression properties. These can also affect the post-compression characteristics, such as the hardness, friability, disintegration, and dissolution of tablets.[8]

2. DRY GRANULATION

The active pharmaceutical ingredient (API) and other excipients are thoroughly blended to create a consistent powder mixture. For chewable tablets, excipients such as sorbitol and dextrose are often included to provide sweetness and an agreeable mouthfeel to the product.

The powder was fed into the compaction unit. There are two main techniques.

A tablet press was used to compress the powder into large tablets (slugs).

The powder is fed between two counter-rotating rollers, which compress it into an uninterrupted ribbon.[9]

This step uses mechanical pressure to bind the powder particles together without the need for heat or solvents.

The compacted ribbons or slugs were then passed through a milling system.

This process breaks the material into smaller, uniform granules of the desired size.

The newly formed granules are blended with any leftover excipients, such as lubricants, to ensure proper flow during the final compression. The final blend was compressed into chewable tablets.[10]

3. WET GRANULATION

1. The drug and excipients were mixed. This includes diluents, binders, and other necessary ingredients.
2. A binder, such as polyvinylpyrrolidone (PVP) or starch, is dissolved in a suitable solvent, such as water or ethanol, to create a granulating solution.
3. The binder solution was added to the powder mixture while it was being mixed to form a wet cohesive mass. The amount of liquid was carefully controlled to achieve a moist mass rather than a paste.
4. The wet mass is forced through a sieve or screen to break it down into granules of the desired size.[11]
5. The granules are then dried using equipment such as a fluid bed dryer or a tray dryer to eliminate the solvent and increase their strength.
6. After drying, the granules were milled or calibrated to achieve a uniform particle size.
7. The dried granules are then blended with additional excipients, such as disintegrants, lubricants, and flavorings, before compression.
8. The final formulation was compressed into tablets using a tablet press.[12]

4. HOT MELT EXTRUSION:

The powder blend was fed into a twin-screw extruder via a feeder.

The extruder heated the mixture in multiple temperature zones. typical temp:

60–180 °C, depending on the polymer and drug stability.

The screws mixed, sheared, and melted the mass to form a homogeneous molten matrix.

the molten mixture exits through a die to form

rods, strips, sheets

Flat ribbons or rods are commonly used for chewable products.

The extrudates are then cooled on a conveyor or cooling belt to solidify [13].

5. FLUID BED GRANULATION

1. The active ingredients, excipients, and binders were weighed and mixed to create a homogeneous powder blend.
2. The powder was loaded into a fluidized bed granulator. A stream of heated air was passed through a perforated plate at the bottom of the chamber, lifting and suspending the particles in a turbulent fluidized state.[14]
3. The binder solution was sprayed through nozzles onto the fluidized particles. The liquid droplets bind the powder particles together to form granules, a process sometimes referred to as wet granulation.
4. The heated air simultaneously dries the wet granules, evaporates the solvent, and solidifies the liquid binder bridges. This is often performed continuously or simultaneously with granulation.[15]
5. Once the granules reach the desired moisture content, they are discharged from the granulator and cooled to prevent caking of the product.
6. The dried porous granules were compressed into final chewable tablet forms. The porous structure of the granules created during the fluid bed process contributes to the rapid disintegration and high solubility of the final tablet.[16]

6. SPRAY DRYING

- The liquid feed is sprayed through an atomizer, creating the active ingredient (API), and the matrix materials are dissolved, suspended, or emulsified in a suitable solvent (such as water or an organic solvent). The solution or suspension was then fed into a spray dryer.[17]

- A fine mist of small droplets is generated using various types of atomizers, including pressure and centrifugal (rotary) nozzles.
- The droplets are exposed to a stream of hot air or inert gas, which instantly evaporates the solvent from the surface of the droplets, forming solid particles.[18]
- Dried powder or granules are collected from the drying chamber, typically using a cyclone or other separation device.
- The collected powder was milled to a uniform size, if necessary. Lubricants, such as magnesium stearate, were added to the powders. The final mixture was compressed into tablets using a tablet press. Finally, the tablets were tested for quality, including hardness, weight variation, and taste.
- The material is deposited layer by layer, with the print head moving along the x-y axes and the build plate moving down the z-axis until the final 3d structure is formed.
- Post-processing (drying/curing): After printing, the "wet" tablets are typically dried (e.g., in a fridge or oven for a set time) to reduce moisture content, which enhances their physical stability, hardness, and shelf life.[19]

7. COMPRESSION COATING

prepare the core: A tablet core is first compressed using a standard or specialized tablet press. Coating preparation: A granular coating mixture is prepared, which may contain active. ingredients or excipients to mask the taste or provide a specific release profile.

compression coating: a specially designed tablet press was used to compress the coating material around the core tablet in a single operation. this is sometimes called "press coating" or "dry coating."

Two-layer tablet formation: This process results in a "tablet in tablet" structure, with the coating material forming a barrier around the core.[20]

1. ENCAPSULATION

The process begins with the selection of appropriate excipients suitable for a chewable format. Ingredients such as mannitol, xylitol, and sorbitol are commonly used for their pleasant cooling mouthfeel.

If the API has a bitter or unpleasant taste, it must be "encapsulated" or coated to prevent contact with the taste buds during chewing.[21]

API particles are coated with a thin polymer layer using techniques such as fluidized bed coating.

The coating is designed to resist dissolution in the mouth but breaks down once in the stomach/intestines.

Other methods include the use of ion-exchange resins, solid dispersions, and the formation of complexes with cyclodextrins.

The taste-masked API and all dry ingredients (fillers and flavorings) were thoroughly blended to ensure dose uniformity.

Compression (tablet formation): The blended mixture is fed into a tablet press, which uses punches and dies to compress the material into individual chewable tablets with specific hardness and friability (resistance to chipping/crumbling).

Finishing (optional): The finished tablets may be dusted with starch to reduce tackiness, polished, or given an additional outer coating for further protection or aesthetic purposes.[22]

EVALUATION TESTING OF CHEWABLE TABLET

ORGANOLEPTIC PROPERTIES

Taste And Flavour

- **Sweetness and flavour**: Tablets should be formulated with sweeteners and flavouring agents to make them acceptable to children.
- **Bitterness masking:** The tablet should be formulated to mask the inherent bitterness of the active drug.
- **No unpleasant aftertaste:** no bitter or unpleasant aftertaste should remain after chewing the gum.

Mouth Feel and Texture

- **Smooth texture:** The product should disintegrate into a smooth texture and not have a gritty or sandy mouthfeel.[23]
- **Easy chewing:** The tablet should be easy to chew and require moderate force.
- **No residue:** It should not leave any undesirable residue in the mouth after chewing and swallowing.

Sensory-Related Properties

- **Size and shape:** The tablet should have a size and shape appropriate for the intended user, making it easy to chew and handle.
- **Colour:** Colour can be used to make tablets visually appealing, especially for children.

Disintegration: The tablet should disintegrate quickly in the mouth to facilitate dissolution.[24]

PHYSICAL TESTS

1. BULK DENSITY

10 An accurately weighed quantity of powder, which was previously passed through sieve # 40 [USP], was carefully poured into a graduated cylinder. Subsequently, after pouring the powder into the graduated cylinder, the powder bed was made uniform. The volume was then measured directly from the graduation marks on the cylinder in millilitres.[25] The measured volume was called the bulk volume, and the bulk density was calculated using the following formula.

bulk density = weight of powder / bulk volume

Fig 1: tap density tester.

2. TAPPED DENSITY

The same measuring cylinder used for the bulk volume was placed in a tap density apparatus. The tap density apparatus was set to 300 taps/min and operated for 500 taps. The volume was noted as (va), tapped 750 times, and recorded as (vb). If the difference between va and vb is not greater than 2%, then vb is considered the final tapped volume.[26] The tapped density was calculated using the following formula.

tapped density = weight of powder / tapped volume

3. CARR'S INDEX AND HAUSNER's RATIO

10, the volume of a known quantity of granules from each batch was measured before and after tapping using a graduated cylinder. The volume before tapping was used to determine the bulk density, whereas the volume after tapping was used to determine the tap density. Furthermore, Hausner's quotient and Carr's compressibility index, used to determine the flow and compressibility properties of granules[27], were obtained from the following equation: Carr's index = (tapped density – bulk density / tapped density) × 100.

Hausner's ratio = tapped density / bulk density

4. ANGLE OF REPOSE

The angle of repose of the powder was determined using the funnel method. The accurately weighed powder was placed in a funnel. The height of the funnel (h) was adjusted such that the tip of the funnel just touched the apex of the heap of powder. The powder was allowed to flow freely through the funnel onto the surface. Evaluation of tablets: The mechanical strength of the formulated and prepared albendazole tablets was evaluated using parameters such as hardness, weight variation, thickness, friability, and disintegration time.[28]

5. TABLET HARDNESS

Hardness is the crushing strength of a tablet, which determines its ease of handling and transportation. Three tablets were used for each formulation in the study. The hardness of the tablets was determined and expressed in kg/cm2. thickness: 14 The thickness of the tablets was measured using a manual vernier caliper and expressed in mm. friability: 15 the friability of the tablet was determined using a Roche friabilator. was expressed as a percentage (%). Ten tablets were initially weighed (w0) and transferred to a friabilator.[29] The friabilator was operated at 25 rpm for four mins. The tablets were weighed again (w). The percentage friability was calculated as% f = {(w – w0)/w0} × 100.

6. DISINTEGRATION

The in vitro disintegration time was determined using a disintegration test apparatus. A tablet was placed in each of the six tubes of the apparatus, and one disc was added to each tube. The time taken for complete disintegration of the tablet, with no palpable mass remaining in the apparatus, was measured in seconds.[30] The in vitro disintegration of the tablets was completed within 15 min.

7. DISSOLUTION

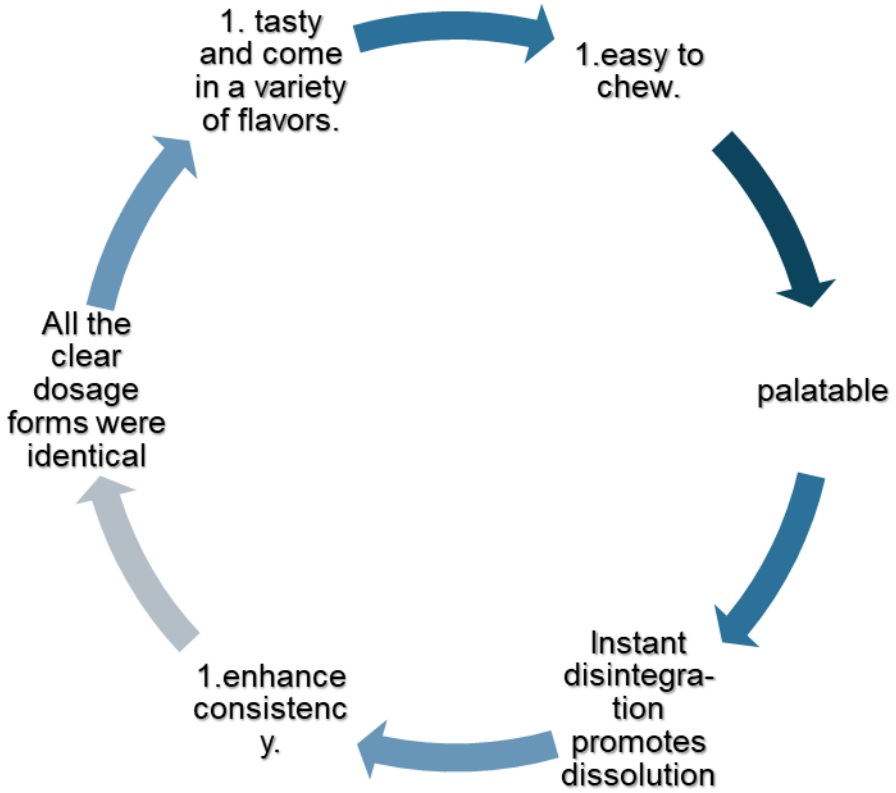
The dissolution of the core tablets of chatechuthe catechu formulation was studied using the USP II dissolution rate test apparatus with a paddle stirrer. A total of 900 ml of 0.1 N HCL was used as the dissolution medium.[31]

ADVANTAGES OF CHEWABLE TABLET

DISADVANTAGES OF CHEWABLE TABLETS

1. Medicines with a very bad taste are difficult to swallow.
2. chewing chewable tablets for a long time can lead to facial muscle soreness
   Proper packaging is essential to ensure the safety and stability of products.
3. They may leave an unpleasant taste in the mouth.
4. Sweeteners such as sorbitol can cause diarrhea, and sucrose can cause tooth decay.
   Chewable tablets require proper packaging to ensure drug safety and stability.
5. The presence of flavourings can cause mouth ulcers. Because it has no mechanical strength, care must be taken when handling it.[32]

IDEAL CHARACTERISTICS CHEWABLE TABLET



EXCIPIENTS USED IN CHEWABLE TABLET

- A diluent is a type of filler used to fill the tablet volume when the tablet is insufficient to fill the volume. Examples.

Mannitol is preferred because of its sweet taste, cooling effect, and noncariogenic properties. Sorbitol and xylitol are used in sugar-free formulations to provide sweetness and a smooth Mouthfeel.[33]

Lactose provides good compressibility but may cause intolerance.

Microcrystalline cellulose (MCC) – improves tablet structure and mouthfeel.

- Binder: Provides cohesion to powdered materials and can be added both dry and wet to form granules

examples

hydroxypropyl methylcellulose (HPMC)

polyvinylpyrrolidone (PVP)

Starch & pregelatinized starch

- Sweeteners: The sweetness profile is adjusted by adding the desired sweetener to the beverage. Sweeteners are added to improve the taste of formulations, especially chewable tablets.
- Natural sweeteners include sucrose, glucose, and fructose.
- Artificial sweeteners: aspartame, saccharin, sucralose, and stevia.
- Sugar alcohols: xylitol and sorbitol.[34]

LIMITATIONS OF CHEWABLE TABLET

1. Drugs with a very bitter or unpleasant taste are difficult to formulate as chewable tablets because taste masking may not be completely effective, leading to poor patient acceptance of the drug.
2. The final product should have a smooth and pleasant consistency. A coarse (e.g., calcium carbonate), chalky, or gummy texture is undesirable and can prevent patients from taking the medication.[35]
3. Large quantities of flavoring and sweetening agents may be required to mask the taste, which could possibly cause mouth ulcers in some individuals with prolonged use.
4. volatile flavours can be lost during the manufacturing process, especially if wet granulation is used, making it challenging to maintain a uniform taste
5. The active pharmaceutical ingredient (API) must be compatible with the excipients used in the formulation, which can limit its use.
6. Very high doses of an active ingredient may be difficult to formulate into a single chewable tablet of a reasonable size.[36]

DEFECTS OF CHEWABLE TABLET

1. Chipping/edging: edges or corners of the tablet break off, often due to insufficient mechanical strength, worn-out tooling (dies/punches), or incorrect setup of the tablet press.
2. Capping and lamination: Capping occurs when the top of the tablet separates from the main body, whereas lamination involves separation of the tablet into layers. These defects can be caused by excessive internal stress, trapped air, or issues with material flow and compression.
3. Sticking and picking: Tablet material adheres to the punch faces or die walls during compression. This is often due to improper lubrication, high moisture content in the granules, or problems with the punch design (e.g., deep engravings).

4. Weight and content variation: Poor powder flow or issues with the die-filling process can lead to inconsistent tablet weights and non-uniform drug content, affecting dosage accuracy.
5. Mottling: uneven color distribution across the tablet surface, usually a result of poor blending of colorants or ingredient incompatibility.[37]

APPLICATIONS OF CHEWABLE TABLET

1. Chewable tablets can release active substances at a controlled rate over an extended period, providing a prolonged local effect.
2. Successful treatment of minor pains, headaches, cold pains, and muscular aches requires rapid absorption of therapeutic doses of the active substance.
3. Chewable tablets as a drug delivery system could be beneficial in minor pain treatment, as buccal absorption results in a fast onset of action and reduces the risk of gastrointestinal side effects.[38]

MARKETED PRODUCT OF CHEWABLE TABLET

BRAND NAME	ACTIVE INGREDIENT	APPLICATION
tums, Rolaids	calcium carbonate	antacid
children's chewable acetaminophen	acetaminophen	analgesic
Bayer chewable aspirin	aspirin	analgesic
Claritin chewable	loratadine	anti-histamine
singular paediatric	montelukast sodium	chronic asthma management
Velphoro	sucroferric oxyhydroxide	chronic kidney disease patients
Limcee	vitamin c	vitamin c supplements for immune support
alka-seltzer	citric acid,aspirin,	antacid and pain relief
pepto-bismol chewable	bismuth subscribecylate	relief of upset stomach, heartburn, nausea, diarrhea.[39]

INTRODUCTION OF CHATECHUCATECHU

Catechu is a natural plant-derived substance obtained primarily from the heartwood of Acacia catechu.

kingdom: plantae

family: fabaceae.

genus: acacia

species: acacia catechu

It is widely known as “katha” and has been used for centuries in traditional systems of medicine, such as Ayurveda and Unani.[40]

catechu is prepared by extracting the heartwood with boiling water, followed by concentration and cooling, resulting in a solid or semisolid mass rich in bioactive compounds. chemically, catechu contains important phytoconstituents such as catechin, epicatechin, tannins, and flavonoids, which are responsible for its therapeutic properties. it exhibits a variety of pharmacological activities including astringent, antioxidant, antimicrobial, anti-inflammatory, and anti-diarrheal effects.[41]

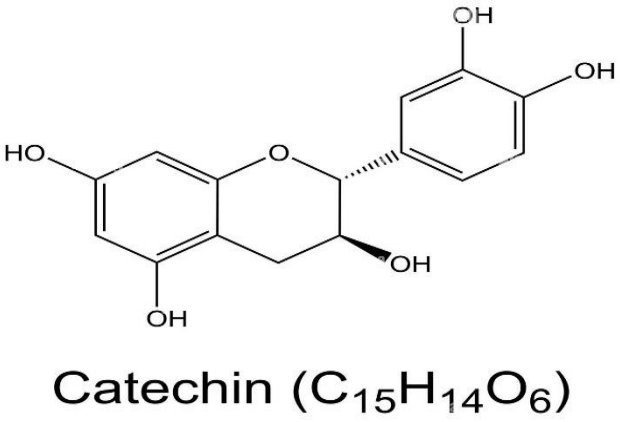
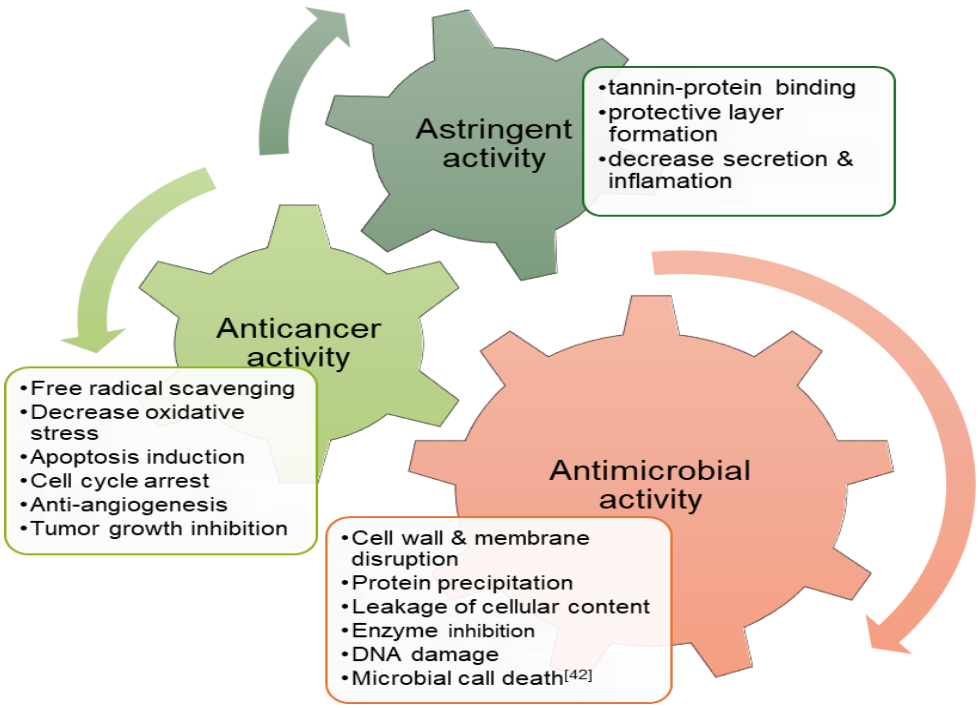


Fig 2: structure of catechin.

MECHANISM OF ACTION



PHARMACOLOGICAL ACTIVITIES

i. Astringent activity: The catechins present in black catechu have astringent activity, making it useful in the treatment of dysentery, diarrhea, and gastrointestinal tract disorders.
ii. Anti-inflammatory activity: Black catechu contains flavonoids and terpenoids, which have been shown to anti-inflammatory properties, making it useful in the treatment of inflammatory diseases such as arthritis and gout.
iii. antioxidant activity: the flavonoids and terpenoids which are present in the black catechu have been antioxidant activity, which makes it very useful in the prevention and treatment of oxidative stress- related disorders such as cancer, and neurodegenerative diseases
iv. antimicrobial activity: black catechu has been traditionally used to trat microbial
v. Infections include antibacterial, antifungal, and antiviral infections.
vi. wound healing: due to its astringent and antimicrobial qualities, it helps to treat wounds
vii. (wound healing) and prevents infections. Cardiovascular health: Studies suggest that black catechu may help manage blood pressure and improve heart health.[43]

ADVANCE IN CATECHU CHEWABLE TABLETS

1. modern formulation use standardized catechu extracts rich in catechin epicatechin.

This compound exhibits strong antioxidant and anticancer activities.

2. direct compression technique -improved the uniformity and stability.
3. chewing difficulty index(cdi)
4. new parameter introduced in research measures the ease of chewing.
5. ensure tablet are

-not too hard

-not too soft

improves patient acceptability.[44]

CONCLUSION

The formulation and evaluation of catechu chewable tablets involve careful selection and optimization of excipients to ensure desirable pre-compression and post-compression properties. Excipients such as microcrystalline cellulose, binders like polyvinylpyrrolidone, and sweeteners contribute to tablet cohesiveness, flowability, palatability, and mechanical strength. Pre-compression parameters including bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose provide critical insights into powder flow and

compressibility, facilitating uniform die filling and consistent tablet weight. Post-compression evaluations such as hardness, friability, disintegration time, and dissolution profile confirm the mechanical integrity and release characteristics necessary for effective therapeutic action. Stability studies affirm the physical and chemical robustness of the chewable tablets under specified conditions, ensuring sustained efficacy throughout shelf life.

Pharmaceutically, catechu offers significant antimicrobial, antioxidant, anti-inflammatory, and astringent properties attributable to its bioactive constituents like catechin, epicatechin, tannins, and flavonoids. These attributes underscore its therapeutic potential in managing various health conditions. The chewable tablet dosage form enhances patient compliance by providing ease of administration, especially for populations with swallowing difficulties, while maintaining stability and controlled release of active compounds. This formulation approach leverages the advantages of chewable tablets, including improved taste masking and rapid onset of action, positioning catechu chewable tablets as a promising herbal pharmaceutical product with considerable clinical relevance.

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