A detailed review on polyherbal chewable tablets

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Due to their ability to produce synergistic effects and take a holistic approach to health and wellness, polyherbal formulations have attracted a lot of interest lately. Chewable tablets have distinguished themselves among the available dosage forms as a practical and patient-friendly alternative, especially for people who have trouble swallowing conventional solid oral dose forms. An overview of the development, formulation, therapeutic uses, and difficulties relating to polyherbal chewable tablets are intended by this review article. Chewable polyherbal formulations mix many plant-derived substances, each with distinct therapeutic qualities, to produce a concoction that targets particular health issues. The review article explains the therapeutic uses of polyherbal chewable tablets in a number of medical specialties, including both contemporary herbal therapy and conventional systems like Ayurveda and traditional Chinese medicine.

Keywords: Synergistic effects. Polyherbal. Chewable tablet. Plant-derived. Conventional.

INTRODUCTION

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Chewable polyherbal tablets are oral dosage forms that include several herbal or botanical extracts. These tablets are designed to be chewed before swallowing in order to release and absorb the active ingredients found in the herbs. The advantages of polyherbal chewable tablets are that they can combine the therapeutic properties of several herbs into a single dosage form. The tablets in combination of many herbs can have a synergistic effect, perhaps improving therapeutic results as compared to utilising individual herbs alone. Depending on the intended use, such as assisting digestion, increasing immunity, alleviating stress, or addressing certain medical disorders, the precise herbal mixture and amount of active ingredients in polyherbal chewable tablets might change. These tablets are frequently used in conventional medical systems, but they are also becoming more widely accepted in contemporary medicine as complementary and alternative treatments (Kushwaha et al., 2005).

The Vedas are full of spells for curing illnesses and charms for driving out the demons who are believed to be the root of illnesses. The oldest branch of medicine, Ayurveda, has been used for thousands of years in India to treat anomalies and describe many elements of life (Kushwaha *et al.*, 2013). There are more than 30 dosage forms that have been discovered based on the ancient literature that is still available, and these are regularly recommended by doctors. The ideal type of product for pharmaceuticals that are taken orally is in the form of solid oral dosage forms. This form of administration was chosen due to its practicality, simplicity, and capacity to mask the disagreeable tastes and odours of plant extracts (Patel *et al.*, 2011; Michael *et al.*, 2013; Agarwal, Kamal, 2007).

Formulations made of many herbs fill the gap between conventional wisdom and cutting-edge scientific inquiry (Marston, 2007; Morris, Gomes, Allen, 2012). Polyherbal mixtures have long been used in traditional medical systems including Ayurveda, Chinese medicine, and Indigenous practices to treat a variety of illnesses. These formulations can be used into contemporary medicine to promote the creation of new treatment choices by fusing conventional knowledge with scientifically supported research (Johri, Zutshi, 1992; Vyas *et al.*, 2001).

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Chewable tablets should be secure and simple to administer to a wide range of patients, including children, adults, and elderly patients, who are unable or reluctant to take whole tablets because of their size or swallowing challenges.

In clinical practice, it's critical to have access to safe, simple dose forms. Many over-the-counter (OTC) and prescription medication medicines come in chewable tablet form. The United States Pharmacopeia (USP) recognizes and distinguishes between two categories of chewable tablets (1) those that can be easily administered by chewing; and (2) those that must be chewed or crushed before swallowing in order to prevent choking and/or to assure the release of the active ingredient.

The main purpose of the present article is to provide an extended review on its therapeutic applications across various health conditions of polyherbal chewable tablets (Shailajan *et al.*, 2011). Based on available evidences this article will also focus on providing safety profile of polyherbal chewable tablets.

BACKGROUND

Polyherbal formulations, which combine many plants or botanical substances in medicinal medicines, have a rich history and are widely used in traditional medical practices all over the world. Across a variety of cultures and civilizations, including Ayurveda, Traditional Chinese Medicine (TCM), Unani, and Native American medicine, these formulas have been utilised for decades, if not millennia. Polyherbal formulations are used because it is thought that combining several herbs might have synergistic therapeutic effects and increase overall efficacy (Ayurvedic Formulary of India, 2003; Kulkarni *et al.*, 2012; Murunikkara, Rasool, 2017).

Polyherbal preparations have been used historically from the dawn of humanity. Texts like the Charaka Samhita and the Sushruta Samhita, which stretch back thousands of years, describe polyherbal compositions in Ayurveda, an old Indian medical practise. Similar to this, TCM uses several polyherbal formulae; classic examples may be found in the Huangdi Neijing (Yellow Emperor's Inner Canon), which dates back over two thousand years. These mixtures frequently have wellknown formulas that have been improved and passed down through centuries (Bhatt, Kedarnagalakshman, Sharma, 2021; Patil, Vishwajith, Gopal, 2012).

The significance of using polyherbal formulations lies in several factors

Synergistic affect

Numerous chemical substances, such as alkaloids, flavonoids, terpenoids, and phenolic compounds, are present in various plants. These substances can interact synergistically when used in particular ratios, boosting their medicinal benefits. When compared to single herb formulations, these interactions may result in higher bioavailability, modification of drug metabolism, and greater absorption.

Multidimensional approach

Formulations made of polyherbs can treat several targets or symptoms at once. These formulations are made to address several facets of an illness or medical condition rather than concentrating on a particular symptom. An herbal remedy for gastrointestinal issues, for instance, can include herbs with anti-inflammatory, antibacterial, carminative, and digesting qualities.

Safety and reduced toxicity

In comparison to single-drug formulations, polyherbal formulations can offer a safer option. It is sometimes feasible to reduce the individual dosages of each plant by mixing many herbs, hence lowering the danger of side effects brought on by using a single herb at excessive amounts. The use of numerous herbs can also counterbalance the risk of toxicity of a certain herb since the formulation's other herbs may lessen its negative effects.

While polyherbal preparations have a rich cultural and medicinal value, it is crucial to remember that their efficacy and safety should be assessed via meticulous scientific research and clinical investigations. Modern scientific techniques may be used to locate active substances, comprehend how they work, and verify the efficacy of medicinal claims made for polyherbal compositions. This blending of conventional wisdom and scientifically supported research can lay a strong foundation for the creation and application of polyherbal formulations in contemporary medicine (Patil *et al.*, 2022).

FORMULATION AND MANUFACTURING

To create an integrative effect and increase therapeutic advantages, various herbs are combined to create polyherbal chewable tablets. There are various factors to take into account while formulating polyherbal chewable tablets and producing them.

Formulation Principles (Maurya, Kumar, 2019)

Herb selection

The choice of herbs is made based on their unique medicinal qualities and interoperability. To provide a synergistic impact, herbs with complimentary properties are used.

Standardization

To keep batch-to-batch uniformity, active components or marker chemicals are discovered and measured.

Dose determination

Based on their medicinal properties and safety profiles, certain plants are given a dose. The goal is to strike the best possible balance between effectiveness and safety.

Regulatory guidelines

The formulation should adhere to legal regulations for labelling, maximum permitted concentrations, and the usage of herbs.

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Manufacturing Methods (Maurya, Kumar, 2019)

Extraction and processing

To acquire the active ingredients from the plants, extraction techniques such as solvent extraction, solvent percolation, and maceration are used. In order to maximise the effectiveness of the extraction, this phase entails selecting the right solvents, temperature, and time.

Commonly used methods in extraction are (Abubakar, Haque, 2020)

Maceration

This is an extraction method in which a container is filled with finely powdered drug material, such as leaves, stem bark, or root bark. The menstruum is then poured on top, covering the drug material entirely. After that, the container is sealed and preserved for a minimum of three days. To achieve thorough extraction, the substance is frequently mixed and, if placed within a container, shaken. Following extraction, the micelle and marc are separated using filtering or decantation. The micelle is then evaporated in an oven or on top of a water bath to separate it from the menstruum. This approach is practical and excellent for using with thermolabile plant material

Infusion

This is a method of extraction similar to maceration. The narcotic substance is ground into a fine powder and put inside a spick-and-span container. The drug material is then covered with the extraction solvent, either hot or cold, and allowed to soak for a brief while. This technique works well for extracting easily soluble bioactive components. Furthermore, it is a suitable procedure for preparing fresh extract for application. Depending on the intended usage, the solvent to sample ratio is typically 4:1 or 16:1.

Digestion

This extraction technique uses a moderate amount of heat throughout the extraction process. Powdered

drug material is added to the extraction solvent in a clean container. At a temperature of around 50° C, the mixture is put over a water bath or in an oven. Throughout the extraction procedure, heat was used to reduce the solvent's viscosity and improve the removal of secondary metabolites. For easily soluble plant components, this approach works well.

Decoctiona

Continuous hot extraction utilizing a predetermined amount of water as a solvent is what this procedure entails. Plant matter that has been dried, ground, and powdered is put into a spotless container. After that, water is added and mixed. The extraction is then accelerated by using heat throughout the process. The procedure just takes a few minutes, often about 15 of them. Typically, the solvent to crude drug ratio is 4:1 or 16:1. It is used to extract plant material that is both heat- and water-soluble.

Drying and powdering

The extracts of herbs are dried to eliminate excessive moisture after extraction. The dried herbal extracts are then broken down into powder form. To achieve homogeneity in the finished product, the powders' particle sizes should be consistent.

Some of the industrial methods of drying include (Emami *et al.,* 2023)

Hot air drying

The most popular drying technique used nowadays is hot air drying. For durable industrial and culinary items, it offers an easy, cost-effective option. However, this method has the potential to fully dry the product surface, which might result in fractures or an uneven outcome. Depending on the product and the permitted drying temperature, it may also be a lengthy procedure.

Sun drying

The oldest and most cost-effective method of drying is by exposing materials to the sun. Although it doesn't retain all of the product's characteristics and vitamins, it is ideally suited for traditional fruits and vegetables drying in isolated places, such as apricots and tomatoes. However, this approach offers little process control and needs a lot of time and space.

Contact drying

This drying technique involves exposing a product to heated walls in order to dry it. For improved uniformity, drying is often done in revolving drums. The main applications of this technology are drying procedures in heavy industries.

However, the dried product may get denaturized if it comes into direct contact with heated walls, and process uniformity is not assured.

Infrared drying

High temperature infrared drying evaporates water or solvent. When the drying effect has to be concentrated on the treated product's surface to also get a roasting effect, it can also be combined with hot air. For things that shouldn't be subjected to high temperatures, this method is far from optimal.

Blending

To guarantee an even dispersion of the active ingredients, excipients are combined with the powdered plant extracts. To increase palatability, this phase may also entail the addition of flavourings and sweets.

Some of the common blending techniques used are (Scheibelhofer *et al.*, 2013)

V blender

The basic idea behind how a V blender machine works is that its cylinders create a "V" shape with an 80

degree symmetry angle. It also contains an apex port that includes a discharge valve. The V-form blender's output is almost completely filled. Because there is no shaft protrusion, cleaning is easy. However, a V blender requires a lot of headroom when fitted. You cannot mix different sizes or densities with it.

Octagonal blender

For finely combining dry grains and powders, an Octagonal Blender is created with an octagonal mixing container and built-in baffles. This blender's sturdy rectangular base and dust-free charging system make it a great choice for usage in labs and at the office. If you're looking for a useful blender for your home or workplace, this one is for you.

Ribbon blender

A ribbon blender is made comprised of an inner and an outer helical ribbon with a horizontal U-shaped trough. The ribbons are angled to move in directions that are diametrically opposed to one another. The agitator tip range typically moves at a pace of 300 feet per minute. When selecting a ribbon blender, the batch volume and product bulk density will determine whether a regular or heavy-duty type is required. The standard bulk density cap for ribbon blenders is 35 lb/cu ft.

Double cone blender

Mixing is one of the most often used procedures in a range of industries, including the chemical, detergent, food, cosmetic, and fertilizer sectors. This is being done to create a consistent bulk combination since each unit has the same quantity of each element. In order to fully blend dry powder and granules, a double cone blender is used. Cone blenders for dry powder mixing and double cone blenders are two distinct pieces of equipment used in diverse industries.

Vertical blender

The vertical blender offers numerous benefits over horizontal blenders. These devices can process a variety of basic materials. They can handle batches as little as 10% of the rated capacity and are transportable to a bag filling station. They also utilize 50% less power and less floor area per unit of material being mixed. They are ideal for multi-story structures because of this.

Granulation

Granulation can be used to increase the flowability and compressibility of the tablet. A binder solution is used to wet the powdered mixture before it is granulated to create the proper size granules.

Some of the common granulation methods include (Shanmugam, 2015)

Dry granulation

When producing tablets, dry granulation is employed when working with wet or heat-sensitive components. The mixture is densified by force as it travels through roller compactors rather than by the use of lubricating agents. The finished sheet is then gently split into flakes, which are subsequently meticulously crushed into granules. Dry granulation is an effective, low-cost production method due to the straightforward equipment, little floor space, and procedures needed. However, there are several obstacles to be solved, like maintaining a uniform distribution of particle sizes and flowability, preventing cross-contamination with dust particles created throughout the process, and more.

Wet granulation

A common method for producing tablets in the pharmaceutical business is wet granulation. In order to have a blend's tiny particles agglomerate into granules of a desired size with the necessary flow characteristics, water or an organic solvent is either sprayed or poured into the mixture. Wet granulation is sometimes a difficult operation that requires several pieces of machinery and procedures including moistening, screening, drying, and sizing. To produce any combination of medicinal component and/or excipients for compression, encapsulation, or filling operations, such as into sachets, wet granulation is essentially the method of choice. The moistening and drying phases are the two basic wet granulation phases. Both processes can be done simultaneously in a fluidized bed granulator or separately by moistening in a high-shear mixer and then drying on trays or in a fluid bed dryer.

Melt granulation

A manufacturing technique called melt granulation is utilized to improve the composition's flow characteristics and boost the homogeneity of the medicine. Melt granulation is typically employed when wet and dry granulation procedures fail to produce the required results. Its benefits include the elimination of a drying stage and a continuous, solvent-free process. In melt granulation, the drug's polymorphism properties, the addition of excipients like surfactants or crystallization inhibitors, the drug's embedding in a solid dispersion, or any combination of these might alter the drug's bioavailability. A dry powder made of the API and excipients is then melted in a melt extruder. Depending on the formulation and the polymers used for melting, the medicine and excipients must withstand temperatures of over 100°C. Throughout the process, which has distinct phases (or zones) based on temperature, mechanical stress levels, densification, and backward movement given to the melt, more liquids can be introduced if necessary to predetermined locations. The agglomerated powder particles are finished granulating once they have cooled, been extruded through a dye, been sliced, and hardened.

Coating

The tablets may be coated to enhance their stability, flavour, and appearance. Sugar, film-forming polymers, or enteric coatings are all acceptable coating ingredients, depending on the formulation's unique needs.

Some common coating techniques include (Salawi *et al.*, 2022)

Film coating

A highly well-liked method due to the abundance of covered items on the market. Film coating entails the application of a thin polymer film on the tablet, capsule, or multiarticulate core, often by spraying.

Sugar coating

This age-old method, which is similar to how confections are coated, has been employed in the pharmaceutical sector since the late 19th century. Through coating machinery, a sucrose-based coating is continuously applied to tablet cores in this unit activity. Water from the syrup evaporates during this process, leaving a thick sugar coating surrounding each pill. Sugar coats are often brightly coloured and sparkly.

Compression coating

This method's use and acceptance in the creation of modified release goods has significantly risen. It is mainly a dry procedure that uses tableting equipment that has been particularly built to compress granules around a prefabricated tablet core.

Quality control

Quality control procedures are used throughout the production process to guarantee that the tablets adhere to predefined standards for weight fluctuation, disintegration time, content homogeneity, and microbiological limitations.

The major benefit of combining the therapeutic benefits of many herbs in a practical dose form is provided by polyherbal chewable tablets. To guarantee the effectiveness, safety, and quality of these goods, it is essential to follow certain formulation principles and production procedures. There are some common excipients used in polyherbal chewable formulations and their roles in those formulations.

In polyherbal chewable tablets, excipients are essential because they help with the formulation in a number of ways, such as by making the product more palatable and increasing patient compliance (Maurya, Kumar, 2019).

Some common excipients and their roles are discussed below (Pharma education, 2023)

Sweeteners

To improve the flavour of polyherbal chewable tablets, sweeteners like fructose, sucrose, or synthetic sweeteners like aspartame and saccharin are added. They make the tablets more palatable by helping to disguise the naturally bitter or disagreeable taste of some botanical components.

Flavouring agents

To enhance the chewable tablet's overall flavour and scent, flavouring agents such natural or artificial flavours are added. They can cover up any lingering bad tastes and offer a flavour that patients would enjoy.

Binders

The components of the tablet are held together and given cohesiveness by binders. They make sure the tablets keep their hardness, integrity, and form. Polyvinylpyrrolidone (PVP) and cellulose derivatives like microcrystalline cellulose and hydroxypropyl cellulose are two common binders.

Disintegrants

Disintegrants speed up the tablet's fast breakdown during chewing and aid in the drug's release in the GI tract. They make sure the tablets dissolve fast so the herbal elements may be liberated and properly absorbed. Crospovidone, sodium starch glycolate, and croscarmellose sodium are typical disintegrants.

Lubricants

During manufacture, lubricants are added to the tablet formulation and the compression machinery to prevent friction. They also assist in preventing tablet sticking and smooth tablet ejection from the compression machine. Talc, stearic acid, and magnesium stearate are examples of typical lubricants.

Diluents/fillers

To enhance the bulk content of the tablets, diluents or fillers are utilised, resulting in consistent tablet weight and enabling tablet compression. Lactose, mannitol, sorbitol, and microcrystalline cellulose are examples of typical diluents.

Antioxidants and Preservatives

Antioxidants can be added to herbal substances to prevent oxidation and deterioration while they are being stored, such as ascorbic acid (vitamin C) or sodium metabisulfite. To stop microbiological development and lengthen shelf life, preservatives like methylparaben or propylparaben can be added.

These excipients can be included in the formulation of polyherbal chewable tablets to provide patients a better taste experience. Enhancing palatability is essential for patient compliance, particularly with chewable tablets, as they are designed to be immediately tasted while being chewed. Patients, especially kids or those who have trouble swallowing, may be more likely to adhere to their medicine schedule if the taste and odour are pleasant.

To guarantee compatibility with the herbal constituents, preserve stability, and adhere to regulatory requirements, it is crucial to highlight that the selection and concentration of excipients should be carefully addressed. Additionally, any particular dietary restrictions, allergies, or sensitivity that patients may have should be taken into mind while choosing the excipients (Pharma education, 2023).

EVALUATION OF TABLET BLENDS (MAHAPATRA, VERMA, 2023)

Angle of repose

The funnel technique was utilised in order to ascertain the angle of repose of tablet mixtures. It was enabled for the mixtures to flow freely via the funnel and out onto the platform. After determining the angle of repose and measuring the diameter of the powder cone, the calculation were used to get the angle.

Tan $\theta = h/r$

Where 'h' and 'r' are the height and radius of the powder cone, respectively.

Bulk density

In order to measure the apparent bulk density, a specific amount of tablet mixture is poured into a graduated cylinder, and both the volume and weight of the cylinder are recorded.

Bulk Density = Mass of powder / Bulk Volume of the powder

Tapped bulk density

To establish it, a graduated cylinder with a known weight of drug-excipient mixture is placed in the appropriate location. The graduated cylinder is dropped onto a hard surface from a height of 10 centimetres at intervals of 2 seconds while being permitted to drop beneath its own weight.

The tapping was carried on until there was no longer any discernible difference in the volume.

Tapped density = Weight of powder / Tapped volume of the powder

Carr's index

The following is how the compressibility index developed by Carr is defined

$$CI = \rho_t - \rho_a / \rho_t = V_a - V_t / V_t$$

Where ρ_t and ρ_a – tapped and poured bulk density; And V, and V_a – tapped and poured bulk volume respectively.

Hausner's ratio

The Hausner's ratio was computed by making use of the formula below, and the results are reported as a percentage.

$H=D_t/D_h$

Whereas D_t represented the density of the powder when it was tapped, D_b indicated the density of the powder when it was measured in bulk.

EVALUATION OF TABLETS (MAHAPATRA, VERMA, 2023)

Thickness

A Vernier calliper was used to measure the thickness of the each tablet, a minimum of 20 tablets of each batches are collected and sampled, and the average thickness of all of the tablets was computed.

Uniformity of weight

Every single tablet that makes up a batch should have the same weight, and any deviation from that weight should fall within the acceptable range. A computerised balance was used to make the measurements, and the results were accurate to within 1 mg. Generally a sample of twenty tablets are used to determine weight control.

Hardness and friability

The Pfizer hardness tester and the Electro lab friabilator test apparatus are used to evaluate each formulation's 20 tablets in order to assess the tablets' levels of hardness and friability, respectively.

Disintegration time

After inserting all six tablets, a plastic disc is placed on top of the tablets and the tubes were sealed. The tablets are subjected to pressure as a result of the disc. In a water medium that is being kept at 37 degrees Celsius, the test tubes were given the freedom to move up and down at a rate of 29-32 cycles per minute.

In vitro dissolution study

The dissolution profile of a polyherbal tablet is commonly evaluated by utilising the USP dissolution equipment II with 900 ml of required buffer solution at 37 ± 0.5 degrees Celsius and a stirring rate of 100 revolutions per minute. Generally, the absorbance of the samples are measured with assistance of UV spectrophotometer after various samples are collected at different time intervals. Simultaneously, the same amount of buffer sample is added to the basket to maintain the balanced amount of buffer solution at time of sample collection. Before measuring the absorbance, collected samples are filtered through Whatman filter paper.

HERBAL INGREDIENTS AND THERAPEUTIC USES

To provide a synergistic effect and improve therapeutic advantages, different herbal substances are combined to create polyherbal chewable tablets. The choice of herbal components is influenced by the intended usage and expected therapeutic outcomes. The following list of typical herbal components can be found in polyherbal chewable tablets

Ashwagandha (Withania sominifera)

An adaptogenic herb called ashwagandha as shown below in Figure 1, is utilised in conventional Ayurvedic treatment. It is well renowned for its calming and revitalising effects. Formulations aimed at boosting energy, reducing stress, and improving general wellbeing frequently contain ashwagandha (Singh *et al.*, 2011).



Ashwagandha Ginger FIGURE 1 – Ashwagandha and Ginger.

Ginger (Zingiber officinale)

Ginger is frequently used in multi-herbal formulations that target gastrointestinal health because of its well-known digestive benefits. It can aid in promoting good digestion and easing nausea and indigestion (Healthline, 2020). The plant of ginger is shown above in Figure 1.

Turmeric (Curcuma longa)

The major ingredient in turmeric, curcumin, is recognised for its antioxidant and anti-inflammatory qualities. It is frequently used in multi-herbal preparations that target inflammation, joint health, and general wellbeing (Healthline, 2020). Turmeric plant is shown below in Figure 2.



TurmericGinkgo BilobaFIGURE 2 – Turmeric and Ginkgo Biloba.

Ginkgo biloba (Ghritakumari)

A well-known plant with cognitive-improving qualities is ginkgo biloba, shown above in Figure 2. It is frequently used in formulations that aim to improve cognitive, memory, and attention skills (Healthline, 2020).

Peppermint (Mentha piperita)

Because of its calming qualities and capacity to ease intestinal problems, peppermint is frequently utilised, plant being showed in Figure 3. It can ease indigestion, cramps, and bloating (National institute of health, 2020).





PeppermintCardamomFIGURE 3 – Peppermint and Cardamom.

Cardamom (Elaichi)

Cardamom is often used as a natural remedy for digestive issues, it also has anti-inflammatory properties and also used to get relieve from respiratory issues (Healthline, 2018). The plant has been shown above in Figure 3.

Cinnamon

It is derived from bark of the tree, shown below in Figure 4, and contains properties like antioxidant, antiinflammatory, antimicrobial, and also helps in cholesterol and blood sugar regulation (Healthline, 2018).



Green tea

Cinnamon FIGURE 4 – Cinnamon and Green tea.

Green tea (Camellia sinensis)

Antioxidant-rich green tea is well known for its benefits to health. It is frequently used in multi-herbal preparations that boost metabolism, control weight, and support antioxidants (Healthline, 2020). The green tea plant is shown above in Figure 4.

Lemon grass (Cymbopogon citratus)

The lemon grass plant shown below in Figure 5, is widely used in Asian cuisine and traditional medicine. It has antioxidant, anti-inflammatory, detoxicating properties, and also helps in stress, fever and cold relief (Medical news, 2018).



Lemon gras FIGURE 5 - Lemon grass and Clove.

Clove (Syzygium aromaticum)

Antioxidants are abundant in cloves, plant shown above in Figure 5. Your body uses these substances to combat free radicals, which harm your cells and can cause disease. The antioxidants in cloves can lower your chance of developing heart disease, diabetes, and several malignancies by eliminating free radicals from your body (Healthline, 2018).

QUALITY CONTROL AND STANDARDIZATION

For polyherbal formulations to be secure in their safety, effectiveness, and consistency, quality control and standardisation are essential. Here are some main arguments in favour of the significance of quality assurance and standardisation

Clove

Safety

The herbal substances used in polyherbal formulations may include contaminants, adulterants, or other impurities that quality control techniques assist to identify and manage. This guarantees that the product complies with strict safety regulations and won't hurt customers (FDA, 2018).

Efficacy and therapeutic benefits

Standardisation makes ensuring that the active ingredients or markers that are responsible for the polyherbal formulation's therapeutic benefits are consistently present at the correct amounts. It guarantees that consumers experience the anticipated health advantages and helps develop a consistent, trustworthy product with recognised potency (WHO, 2015; FDA, 2018).

Consistency and reproducibility

Processes for quality assurance and standardisation aid in maintaining uniform product quality across various production facilities or batch sizes. Due to this, every batch of the polyherbal formulation is guaranteed to provide the same level of quality, safety, and effectiveness, independent of when or where it was made. Building confidence among medical providers and patients requires consistency (WHO, 2015; FDA, 2018).

Regulatory compliance

For polyherbal compositions, regulatory bodies frequently demand adherence to certain quality control and standardisation practises. In order to get regulatory clearances and adhere to pertinent legislation, as well as to ensure that the product may be sold and promoted lawfully, it is imperative to fulfil these standards (Tripathi *et al.*, 2017).

Quality assurance

Testing the raw materials, intermediate goods, and final formulations are examples of quality control

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procedures that may be used to detect any deviations from the stated quality standards. Manufacturers may guarantee that their polyherbal formulations match the established quality requirements by putting in place effective quality control systems, which lowers the likelihood of product recalls or quality-related problems (Tripathi *et al.*, 2017).

Research and development

The standardisation of polyherbal formulations makes it easier to conduct and advance scientific study. Researchers can examine a formulation's pharmacological characteristics, carry out clinical studies, and investigate novel uses or combinations of herbal constituents more successfully when the content and quality of the formulation are known and consistent (Tripathi *et al.*, 2017).

Adherence to regulatory concerns and standards established by regulatory bodies is necessary to guarantee the safety and effectiveness of polyherbal chewable tablets. Here are some important factors to think about

Regulatory authority guidelines

Regulatory agencies from many nations are in charge of vetting the efficacy and safety of pharmaceuticals, including herbal remedies. It is essential to review the detailed instructions supplied by the appropriate regulatory authorities in your nation or area. The World Health Organisation (WHO) recommendations, the European Medicines Agency (EMA), and the U.S. Food and Drug Administration (FDA, 2018) are a few examples (WHO, 2018).

Good manufacturing practices

Good Manufacturing Practices must be followed in manufacturing facilities to guarantee the consistency of polyherbal chewable tablets' quality, safety, and effectiveness. GMP regulations specify in great detail what must be done in terms of personnel, facilities, tools, manufacturing procedures, quality assurance, records keeping, and product storage (WHO, 2018).

Ingredient quality and authentication

Polyherbal chewable tablets must be made with high-quality, genuine herbal components. In order to confirm the authenticity, purity, and potency of each plant, comprehensive quality control testing must be conducted. It's crucial to keep track of component origins, obtain certifications of analysis, and follow international and U.S. pharmacopeialstandards (Zarvandi *et al.*, 2017).

Safety assesment

The polyherbal chewable tablets need to have their overall safety evaluated. This include assessing potential negative effects, toxicity, and drug interactions. To evaluate the safety profile of the product, preclinical and clinical research, including toxicity testing, should be carried out (Palla *et al.*, 2021).

Efficacy evaluation

To show they provide the advantages they promise, polyherbal chewable tablets should be put through an effectiveness review. Performing preclinical and clinical research, together with the right endpoints, study designs, sample sizes, statistical analysis, and data interpretation, is necessary to determine the product's efficacy (Tripathi *et al.*, 2015).

Stability testing

To evaluate the shelf life and storage requirements of polyherbal chewable tablets, stability testing is essential. It entails assessing the product's stability over a predetermined time period under various environmental circumstances (temperature, humidity). The effectiveness, quality, and safety of the tablets are maintained over the stated shelf life thanks to stability testing (Zarvandi *et al.*, 2017).

Labelling and packaging

Polyherbal chewable tablets must have accurate and detailed labelling. The product's name, contents, dosing directions, cautions, contraindications, storage requirements, batch number, production date, and expiration date should all be listed on the label. Tablets should be shielded from moisture, light, and other environmental elements by tamper-evident packaging (Tripathi *et al.*, 2015).

To guarantee compliance with all applicable laws and regulations that are particular to your nation or region, it is crucial to speak with regulatory specialists and get advice from the appropriate regulatory body.

CLINICAL APPLICATIONS AND FUTURE PERSPECTIVES (PALLA ET AL., 2021, PATIL ET AL., 2022)

Chewable tablets are frequently used in the treatment of many disorders because they are convenient and simple to administer, particularly in children and geriatrics. Some of the marketed formulations of chewable tablets are given in Table I.

S. No.	Marketed Product	Manufacturing Company	Therapeutic Uses
1.	Organic ginger tablet	HCR ayurveda	Throat infections
2.	Vitamin c and zinc chewable tablets	Root cure organics	To treat hair problems
3.	In fresh bad breath	Infresh products	To treat bad breath

TABLE I - List of some marketed chewable tablets

S. No.	Marketed Product	Manufacturing Company	Therapeutic Uses
4.	Kofabid chewable tablets	Aarogyam the wellness store private limited	Cough, sore throat and other throat problems
5.	Wellchew herbal chewable tablets	One wellness international Pvt.Ltd.	To maintain healthy bones and teeth
6.	Orosoft chewable tablets	Innovative pharmaceuticals	To treat mouth ulcers
7.	Colfrin - H	Cooper pharma limited	Cold and Flu control
8.	Khuli saans	Psychocare Health Private Limited	Dry cough and cold
9.	Smokill	Novel nutrients	Relieves from Smoking
10.	Orobest	Ikon remedies Pvt. Ltd.	To treat mouth ulcers

TABLE I - List of some marketed chewable tablets

Here are a few typical conditions for which chewable tablets are used in medicine:

Pediatric medicine (Michele et al., 2002)

Vitamin and Mineral Supplements

Children who may have trouble swallowing pills are frequently given vitamins and minerals in the form of chewable tablets.

Antibiotics

Some antibiotics are formulated as chewable tablets to make it easier for children to take their medication.

Allergies

Children with allergy symptoms are frequently treated with chewable antihistamine pills.

Dental Health

Children's dental cavities are prevented with chewable fluoride tablets

Gastrointestinal disorders

Antacids

Chewable antacids with ingredients like calcium carbonate offer prompt relief from indigestion and acid reflux.

Anti-diarrheal Drugs

Some chewable tablets have active components that help with diarrhoea symptoms.

Nutritional supplements (Nyamweya, Kimani, 2020)

Calcium supplements

Chewable calcium tablets are frequently administered to people with osteoporosis or calcium shortage.

Iron supplements

Chewable iron tablets are used to treat anaemia caused by an iron deficiency.

Infectious diseases

Antiviral Drugs

Some antiviral drugs are available in chewable forms, which makes it simpler for patients to follow their treatment plan.

Antimalarial Drugs

Chewable antimalarial pills are used for both treatment and prevention of malaria in areas where the disease is common.

Psychiatric disorders (Sarris, 2018)

Antipsychotic Drugs

For individuals who have trouble swallowing, several antipsychotic drugs are offered in chewable form.

Medication for Attention Deficit Hyperactivity Disorder (*ADHD*)

For kids who have trouble swallowing tablets, chewable forms of ADHD drugs are available.

Pain and inflammation (Crofford, 2013)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Chewable NSAID pills offer pain and inflammation relief, and they are frequently used to treat illnesses like arthritis.

Traveler's health (DuPont *et al.*, 1987; Toussaint *et al.*, 2021)

Motion Sickness

Chewable tablets that contain motion sickness remedies are helpful for travellers.

Altitude Sickness

Chewable tablets containing a particular drug can help avoid altitude sickness symptoms.

Oral health (Hellwig, Lussi, 2006)

Thrush

Oral thrush is treated with chewable antifungal pills.

Gingivitis

Chewable antibacterial agent-containing tablets can be used to treat gingivitis.

Chewable tablets offer a practical alternative for patients who have trouble swallowing traditional tablets or capsules. However, it's vital for patients to follow their healthcare provider's advice about dose and administration to guarantee the medication's effectiveness and safety.

IDEAL CHARACTERISTICS OF CHEWABLE TABLETS (GAIKWAD, THORAT, 2023)

They are simple to bite.

They are palatable.

They break down fastly and enhance dissolution.

Helpful for the patients who experience challenges while swallowing ordinary tablets.

They are helpful in improving consistency. Convenient to take, anywhere and at any time.

ADVANTAGES OF CHEWABLE TABLETS (GAIKWAD, THORAT, 2023; RENU ET AL., 2015)

Patient convenience.

They provide better absorption characteristics. Children friendly because of lovely taste.

Chewable tablets offer more preferences over the greater size of dosage forms that are hard to swallow.

By biting in the mouth to reduce size and avoid disintegration before being ingested, therapeutically active agents' effectiveness is increased.

DISADVANTAGES OF CHEWABLE TABLETS (GAIKWAD, THORAT, 2023; RENU ET AL., 2015)

Chewable tablets are not made for bitter-tasting medications.

Due to the increased usage of flavour enhancers in chewable tablets, there is a chance that an oral cavity ulcer will develop.

Chewable tablets contain a variety of excipients to add bulk and enhance tablet properties, however certain excipients are harmful to the body, such as sorbitol, which causes diarrhoea and flatulence.

Long-term chewing of chewable tablets causes face muscle soreness.

Because many chewable tablets have hygroscopic qualities, they require dry storage conditions and precise packaging.

RECENT DEVELOPMENTS IN POLYHERBAL CHEWABLE TABLETS FORMULATIONS (DUBEY, DIXIT, 2023)

Ayurveda, one of the oldest medical systems, has a history dating back to 5000 BC, and scientists are currently exploring the development of novel polyherbal therapies or utilising old traditional polyherbal formulations that have been utilised for many decades.

Digestive health

By mixing herbs with digestive qualities, polyherbal chewable formulations can be utilised to enhance digestive health. These formulas could facilitate better digestion, lessen bloating, ease constipation, and calm an upset stomach.

Immune support

When mixed in a polyherbal chewable formulation, certain herbs with immunomodulatory qualities can aid in boosting the immune system. These formulations may promote general immune function and strengthen the body's defence systems.

Nutritional supplementation

Chewable polyherbal formulations may be created to deliver a variety of vital elements, including vitamins, minerals, and antioxidants. They may be an easy and tasty option to add to your diet and make sure you're getting enough essential nutrients.

Respiratory health

To maintain respiratory health and relieve the symptoms of respiratory disorders, several herbal substances have been employed historically. Chewable polyherbal formulations may mix these herbs to ease coughing, clear up congestion, and support respiratory health.

Stress relief and relaxation

In order to manage stress, anxiety, and promote relaxation, several plants have adaptogenic and anxiolytic qualities. Such herbs may be used in polyherbal chewable formulations that offer a simple and all-natural way to enhance mental health.

Oral health

Some herbs contain calming, anti-inflammatory, and antibacterial qualities that might be helpful for dental health. Polyherbal chewable formulations intended to support oral health may assist to lessen plaque development, improve gum health, and freshen breath.

Joint and skeletal support

The management of joint pain, inflammation, and the promotion of musculoskeletal health may be aided by polyherbal chewable formulations including herbs with analgesic and anti-inflammatory characteristics. For people with arthritis or other musculoskeletal disorders, they may be helpful.

Antioxidants and anti-aging benefits

Numerous herbs have anti-oxidant characteristics that assist prevent cellular damage and battle oxidative stress. Antioxidant-rich polyherbal chewable formulations may help slow the effects of ageing and enhance general health.

Menstrual health

It is well known that some herbal substances can improve menstruation health and reduce related pain. Menstrual cramp relief, hormone balance, and support for a normal menstrual cycle may all be provided by polyherbal chewable formulations.

Children's health

To address a variety of health issues, children-specific polyherbal chewable formulations can be created. In a kidfriendly way, they can support nourishment, raise immunity, facilitate digestion, and advance general wellbeing.

It's crucial to keep in mind that precise formulas may change according on the intended application and the herb combination employed. Before utilising any polyherbal chewable formulation, it is advised to speak with a healthcare provider or herbalist to establish safety and suitability for particular requirements.

CONCLUSION

Chewable tablets are crucial in the pharmaceutical sector and have several benefits that make them useful in healthcare. Their chewable shape improves patient compliance, particularly for people who have trouble swallowing conventional tablets or capsules, such kids, seniors, and patients with certain medical issues. Chewable tablets promote medication adherence and make sure that patients receive their prescribed therapy properly by offering a more practical and pleasurable form of administration.

Additionally, chewable tablets are sometimes given tasty flavours to appeal to kids and lessen their reluctance to taking medicine. This aspect is especially important in paediatric medicine, where it can be difficult to get a youngster to cooperate with taking medicines. Chewable tablets make it simple for parents or other carers to make sure that kids take their prescribed prescriptions without complaining or feeling uncomfortable because of how easily they can be administered and how delicious they taste.

Chewable tablets are anticipated to keep becoming more significant and practical in the future. Chewable tablets are a crucial alternate dose form for senior patients since the prevalence of dysphagia (difficulty swallowing) and other swallowing issues may rise as the population ages. Additionally, improvements in pharmaceutical technology are probably going to result in the creation of more inventive and complex chewable tablet compositions, enhancing the effectiveness and bioavailability of different medications.

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