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A Review Article on dosage forms of Herbal Products and Storage Conditions

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ABSTRACT:
Stability studies are crucial for assessing herbal products' quality and making sure they are safe and effective for the duration of their shelf lives. Testing for stability entails assessing a product's physical, chemical, and microbiological attributes throughout time under various storage conditions, such as temperature, humidity, and light exposure. The findings of stability studies can be used to assess a product's shelf life and to assist manufacturers in choosing the best packaging, labelling, and storage options.
Herbal products, which can be vulnerable to environmental influences and degrade over time, impacting their safety and efficacy, are especially in need of stability studies. Herbal products must undergo stability testing before being approved for marketing by regulatory organisations all over the world.Important data from this testing can be utilised to determine the right shelf-life and storage conditions and to guarantee that the product is still safe and functional for consumers. To ensure that their goods are safe and effective for consumers, manufacturers of herbal products should adhere to the regulations set forth by various regulatory authorities.
Keywords: Storage conditions, herbal products, and herbal dose forms.

I. INTRODUCTION-

Herbal medicinal products (HMPs) are becoming increasingly popular worldwide, with about 80% of the world's population, especially in developing countries, using them as part of their primary healthcare needs. In Ghana, it has been estimated that 70% of the population use herbal medicinal products either alone or in combination with allopathic medicines.

HMPs are defined as plants, parts of plants or extracts from plants that are used in healthcare or in combating the disease. They can be processed and used in different ways and forms, including whole herbs, teas, syrups, essential oils, ointments, liniments, capsules, and tablets.

Large-scale manufacture of HMPs is becoming more routine, which may result in longer storage times and possible product deterioration. Stability studies are essential in determining product shelf-life and enhancing product quality. Stability studies may involve physical or sensory tests, microbiological tests, and chemical or chromatographic/spectral tests.

Determining the chemical stability of a herbal preparation can be challenging due to the fact that a plant extract may contain many different compounds. Additionally, plant enzymes such as esterases, glycosidases or oxidases play a prominent role in the decomposition of secondary plant metabolites.

This article provides an overview of the various herbal dosage forms currently available and their stability considerations. It is important to note that while HMPs may have potential therapeutic benefits, they should be used with caution as they can interact with conventional medications and may cause adverse effects. It is always recommended to consult with a healthcare professional before using HMPs.

Dosage forms of herbal medicinal products

Dosage forms are the means by which drug molecules or plant parts are delivered to sites of action within the body. Herbal dosage forms can be administered through various routes including oral, rectal, topical, parenteral, respiratory, nasal, ophthalmic and otic. Categorization of finished herbal products into dosage forms can help define specific protocols for quality control and stability testing.

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Herbal medicinal products are defined as finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations. These products may also contain excipients in addition to the active ingredients. Medicines that contain plant materials combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines.

Finished herbal products or herbal drug preparations can take various forms, and various solvents may be used for their extraction, distillation, expression, fractionation, purification, concentration, or fermentation. These forms include comminuted or powdered herbal drugs, tinctures, extracts, essential oils, expressed juices, and processed exudates.

It is important to note that different dosage forms can affect the bioavailability and pharmacokinetics of the active ingredients, which can in turn affect the therapeutic efficacy of the herbal product. Therefore, it is crucial to understand the properties and characteristics of each dosage form and to conduct appropriate stability testing to ensure product quality.

Decoctions:

Thank you for the additional information on decoctions. It is interesting to note that decoctions are commonly used in traditional herbal medicine, especially for hard plant materials such as barks and roots. They are also suitable for herbs with sparingly soluble constituents. Decoctions are normally intended for immediate use, but can be stored for a limited period if necessary. Excipients such as preservatives may be added to prevent spoilage, but stability testing should be conducted to determine the shelf-life of the product. Sweeteners such as syrup or honey may also be added to decoctions.

It is also notable that the decoction process can influence the amount of active components in the final product. A study on Sijunzi decoction, a Chinese herbal remedy consisting of Panax ginseng, Poria cocos, Atractylodes macrocephala, and Glycyrrhiza uralensis, found that the concentration ratios of major active components in the individual herbs were different from those in the decoction. This suggests that the decoction process can impact the number of active components in the final product.

Finally, it is interesting to note that the chemical stability and activity of decoction extracts can vary depending on the storage conditions and preparation method. For example, a study on Cassia fistula pod pulp found that the decoction extract was chemically stable after 6 months of storage under certain conditions, but had low anti-dermatophyte activity compared to a hydrolyzed mixture. This highlights the importance of conducting stability testing and considering the potential impact of the preparation method on the final product.

Tinctures:

In summary, tinctures are plant extracts made by macerating plant parts in a water-ethanol solution. The wide chemical diversity of plant constituents demands quality control analytical tools optimized for the detection of single chemical compounds or a specific group of compounds. NMR and MS have been successfully used to obtain a metabolic fingerprint to distinguish between different commercial tinctures, assess batch to batch homogeneity and evaluate the product degradation after the expiry date of the batch. The alcohol in a tincture act as a preservative, allowing the extract to be kept for several years. The recommended alcohol content of a tincture varies depending on the type of constituents being extracted. The shelf-life of tinctures can range from around five years for properly stored tinctures to as little as six months for certain types of tinctures. It is important to properly store tinctures to maintain their quality and potency. Storage conditions can affect the chemical composition of tinctures, including the decarboxylation of Δ9-tetrahydrocannabinolic acid A (THCA) to Δ9-tetrahydrocannabinol (THC) in the tinctures of Cannabis sativa L.

Herbal glycerites:

Glycerites are a type of herbal extract that use glycerine as the solvent instead of alcohol and water. Glycerine is a sweet, syrupy liquid that is commonly used in food and pharmaceuticals. It is a good alternative to alcohol for those who cannot consume it, such as children or those with alcohol sensitivities.

When making a glycerite, the herbs are usually chopped or ground and then mixed with glycerine. The mixture is then allowed to sit for several weeks to allow the glycerine to extract the active compounds from the herbs. The resulting

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product is a sweet-tasting liquid that can be taken orally.

Glycerites have several advantages over alcoholic extracts. They are safe for children and those who cannot consume alcohol. They are also less harsh on the digestive system than alcohol. However, glycerites are typically less potent than alcoholic extracts, and their shelf life is shorter.

Glycerites are best suited for herbs that do not contain resins or gums. For herbs that contain these compounds, alcohol is needed to properly extract the active constituents. Glycerites should also be refrigerated for best results and should be used within six months to two years.

Glycerine is also useful for preserving fresh plant juices. When half fresh plant juice and half glycerine are mixed, the resulting preparation is called a succus. Glycerine is particularly good for soothing preparations intended for the throat and digestive tract, or coughs. Overall, glycerites are a useful alternative to alcoholic extracts for those who cannot consume alcohol or prefer a sweeter-tasting herbal preparation.

Herbal alcoholic beverages (bitters/wines):

It is common for herbal alcoholic beverages to be made from ethanolic or hydroethanolic extracts of herbal material, and they are consumed orally as a beverage. These types of beverages are popular in various regions, including Africa, Southeast Europe, and the Mediterranean, and are often used for their medicinal properties, which depend on the type and quantity of herbs used in the preparation.

The alcohol present in the beverage serves as a preservative, which helps to prolong its shelf-life compared to other types of herbal preparations, such as decoctions and infusions. The antioxidant, antibacterial, and antifungal properties of the beverage, as well as its total phenolic and flavonoid content, can depend on the storage conditions and duration of the product.

Research has shown that the tithable acidity, pH, and percentage alcohol content of pasteurized, noncarbonated, alcoholic orange juice beverages remained constant during storage at various temperatures for up to 14 weeks. However, the accumulation of furfural and the darkening of the beverage during storage indicated a degradation of ascorbic acid in the product.

Oxymels:

That is correct. An oxymel is a preparation made by combining honey and vinegar. The resulting mixture is both sweet and sour, and it is often used as a carrier for herbal extracts, infusions, decoctions, and concentrates. Oxymels are commonly used as a gargle, and they can also be used to deliver potent herbal remedies, such as garlic, cayenne, and lobelia.

The stability of an oxymel can vary depending on the specific formulation used, including the content of honey and vinegar, as well as the preparation for which it is being used as a carrier. For example, an oxymel used to deliver a concentrated herbal remedy may have a different stability profile compared to one used as a simple gargle. As with any herbal preparation, it is important to follow recommended dosages and storage guidelines to ensure the stability and efficacy of the product.

Herbal capsules:

Thank you for sharing this information about herbal capsules. It's interesting to learn about the benefits and stability of this type of dosage form for herbal ingredients.

Capsules can be a convenient and effective way to deliver herbal supplements to the body, especially for those who may have difficulty swallowing tablets or who dislike the taste of liquid preparations. The gelatin shell of the capsule can help mask the taste and odor of the herbal material, making it easier to take.

It's also worth noting that capsules can provide a uniform dosage of the herbal ingredient, which can be important for achieving consistent therapeutic effects. This is because the contents of the capsule are typically finely milled or in the form of extracts, which ensures that the active components are evenly distributed.

Finally, it's good to know that herbal capsules can have a relatively long shelf life and be stable under various storage conditions. It's important to conduct stability studies to ensure that the product remains effective and safe for use over time.

Herbal tablets:

Thank you for the information about tablets and herbal tablets. It is important to consider the excipients and formulation additives used in tablet production to ensure efficient tableting, disintegration, taste masking, and visual appeal. Coatings can also be applied to tablets to protect the drug from stomach acid and increase its shelf life.

Herbal tablets are designed for oral use and contain various herbal materials for therapeutic effects. The

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herbal materials can be incorporated into the tablets in the form of finely powdered and sifted plant material or extracts using suitable solvents for oral use. It is crucial to determine the stability of herbal tablets as storage conditions can affect their shelf life.

For example, herbal tablets containing Rhodiola rosea L. extract were found to be stable during six months of storage at 25 °C/60% RH. However, they failed the stability test at 40 °C/75% RH due to decreased hardness. It is essential to consider storage conditions and conduct stability tests to ensure the efficacy and safety of herbal tablets.

Herbal ointments:

It is true that ointments are semi-solid preparations that can be used for various purposes, such as emollients or delivering medicaments to the skin or mucous membranes. The base of an ointment is typically anhydrous and hydrophobic, which means it does not mix well with skin secretions. Herbal ointments are a type of ointment that contain plant materials in either finely sifted or extracted form incorporated into the base.

However, it is important to note that herbal ointments should not be used for deep wounds, as they may not provide the necessary protection and may even lead to infection. Additionally, the presence of herbal materials in an ointment may cause it to deteriorate more quickly than other types of ointments, making it necessary to provide appropriate labeling instructions for storage and shelf-life.

To determine the stability of an herbal ointment containing tinctures of calendula and arnica for the treatment of hemorrhoids, a stability-indicating thin-layer chromatography technique was used. It was found that the shelf-life of the ointment was one month at 25°C±2°C/60% RH and two months at 5°C±3°C when protected from light. This information is important for ensuring that the ointment remains effective and safe for use over time.

Herbal balms:

These may be classified as ointments meant for massage into the skin for relief of body aches and pains. They normally contain herbal materials which provide arubefacient effect on the skin and by so doing cause relief of pain. The stability of herbal balms may be compared to that of herbal ointments since the bases for preparation are similar. The difference arises in the type of herbal material beingused to exert a particular effect.

Herbal creams:

Contain the herbal material in either finely sifted formor incorporated as an extract. Creams normally contain antimicrobial Creams are semi-solid emulsions that are mixtures of oil and water (hydrophilic). Herbal creams normally preservatives due to the presence of water in the base and may have a relatively shorter shelf lifecompared to ointments . Some herbalists tend to confuse creams and ointments. Herbal creams are those which have a hydrophilic base. If the base is purely hydrophobic, then the preparation must be qualified as an ointment.

Herbal oils:

These are suspensions or solutions of herbal materials in an oily vehicle. Infused oils are often called macerated oils, and should not be confused with essential oils, which are aromatic oils isolated by distilling the plant material. These preparations are normally meant for external or topical use as liniments. In a few cases, however, some of these preparations may be meant for oral use . Herbal materials such as leaves with essential oils may normally be found incorporated in these oils Thestability and shelf life of a herbal oil depends largely on the type of oil being usedin the extraction process since the stability of various essential oils differs.

Herbal soaps:

That's correct! Soaps are typically made through a process called saponification, which involves combining a fatty acid with an alkaline substance, such as caustic soda, to create a salt that we commonly know as soap.

Herbal soaps are formulated with natural ingredients, such as herbs, essential oils, and botanical extracts, that are believed to have beneficial effects on the skin. These ingredients can have antimicrobial, antifungal, and antibacterial properties, which help to cleanse and soothe the skin while providing other therapeutic benefits.

To increase the shelf-life of soaps, preservatives or antioxidants can be added to prevent the growth of bacteria or other microorganisms that can cause spoilage. However, many natural soaps do not contain preservatives, and their shelf-life can vary depending on the specific ingredients and how the soap is stored.

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Herbal teas:

It seems that you are referring to the preparation of herbal teas. These teas can be made using either tea bags or powdered herbal materials. When making an infusion, the herbs are steeped in hot water for a few minutes before being consumed. It is important to drink the tea immediately after preparation, as it does not store well due to the use of water in the extraction process.

The stability of the powdered plant material used in the preparation depends on several factors, such as the type and nature of the herbal material, as well as the moisture content of the powder in the bags and packaging. The shelf life of the tea also depends on how finely the herbs have been crushed and the storage conditions.

If stored in airtight containers, herbal teas can last for up to a year. However, if stored in tea bags, the shelf life may be shorter. It is important to follow the storage guidelines provided on the packaging to ensure the tea stays fresh for as long as possible.

Herbal powders:

It seems like you have provided information about powdered herbal materials that can be used directly or incorporated into foods, beverages, insufflations, and for treating wounds. The powder may contain finely sifted herbal materials from different parts of plants, which are intended to provide a particular therapeutic effect. The stability of the powder depends on various factors, such as the type and nature of the herbal material and the moisture content of the powder in the packaging.

You have also mentioned an example of a specific plant, Nauclea latifolia S. M., which is an antimalarial plant found in Africa. The dried herb and extract of the root of this plant were found to be stable under tropical room temperature conditions for over one year in sealed glass containers. This indicates that the stability of herbal powders may vary depending on the specific plant and the storage conditions.

Herbal pessaries:

Yes, that is correct. Pessaries are small, solid, oval-shaped objects that are designed to be inserted into the vagina for local or systemic effects. They are typically made from a combination of waxes, oils, and other materials that allow them to dissolve slowly when exposed to body heat.

Herbal pessaries, as you mentioned, are made using a glycerate-gelatin base, which allows them to release herbal ingredients when exposed to body heat. This can provide localized or systemic effects depending on the specific herbs used.

The stability of pessaries is an important factor to consider, as they must be able to maintain their shape and effectiveness over time. Factors such as temperature, humidity, and exposure to air can all affect the stability of pessaries. Therefore, manufacturers must carefully consider these factors when designing and producing pessaries to ensure their stability and effectiveness.

Poultices and Herbal plasters:

Yes, that is correct. Poultices are a type of herbal preparation that involves mashing fresh herbs and applying them directly to the affected area of the skin. The mashed herbs are typically wrapped in gauze or another type of cloth and applied to the skin once the temperature is suitable for application.

Poultices are often used externally to provide relief for a variety of conditions, such as muscle tension, minor skin eruptions, insect bites, superficial wounds, and inflammation. The herbs used in poultices can provide a range of benefits, including soothing and relaxing effects, as well as anti-inflammatory and antimicrobial properties.

Because poultices are made from fresh herbs, they should be used immediately after preparation and cannot be stored for later use. This is because the active compounds in fresh herbs can degrade quickly over time, and the poultice may become less effective or even spoil. Therefore, it is important to prepare poultices fresh each time they are needed.

Herbal baths:

The statement you provided describes the use of herbs in bath water for relaxation and stress relief. The addition of fresh or dried herbs, as well as herbal infusions or tinctures, can impart beneficial properties to the bath water. Aromatic herbs that contain essential oils are commonly used for this purpose, as the oils can be absorbed through the skin and inhaled during the bath, promoting relaxation and stress relief. Examples of such herbs include lavender, chamomile, rosemary, and peppermint. It is important to note that while herbal baths can provide therapeutic benefits, individuals should consult with a healthcare professional before using them, particularly if they have any underlying medical conditions or are pregnant.

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Herbal lozenges:

Lozenges are a type of medicinal formulation designed to slowly release medicinal properties in the mouth. They are typically made by mixing powdered herbs with sweet-tasting excipients such as sugar and honey, and binding agents such as gums (Acacia and tragacanth) and the white of an egg.

One of the main uses of lozenges is to soothe soreness in the throat and help in the treatment of throat infections. Unlike tablets, lozenges typically do not contain disintegrating agents, which means they dissolve slowly in the mouth, releasing their medicinal properties over a longer period of time.

When it comes to shelf life, lozenges are similar to tablets but should be evaluated using an appropriate stability protocol. This protocol will typically involve subjecting the lozenges to a range of environmental conditions (such as temperature and humidity) to assess their stability over time.

Overall, lozenges are a popular and effective way to deliver medicinal properties to the mouth, and can be used for a variety of purposes, including treating sore throats, coughs, and other respiratory conditions.

Storage Conditions

Ambient Temperature:

It is generally recommended to perform testing at temperatures near 25°C, as this is a common temperature range for many medications to be stored and used. However, if the pharmacist has access to an environmental chamber, it is recommended to store the units at the temperature conditions recommended by the International Council for Harmonisation (ICH), which is 25°C ± 2°C. This is because environmental factors, such as temperature and humidity, can have an impact on the stability and efficacy of medications over time. By storing and testing medications at the recommended temperature conditions, pharmacists can help ensure that their patients are receiving medications that are safe and effective.

Refrigeration:

It is common practice in the pharmaceutical industry to evaluate the stability of a drug product under different storage conditions to assess its shelf life and to ensure that it remains safe, efficacious, and of high quality throughout its intended shelf life. In some cases, refrigeration may be recommended as a storage condition to maintain the stability of the drug product.

Furthermore, some active pharmaceutical ingredients (APIs) may be known to be thermosensitive, meaning that they can degrade rapidly when exposed to high temperatures. In such cases, it is important to evaluate the stability of the drug product under refrigerated conditions to ensure that the API remains stable.

If analyses performed at 25°C show a rapid degradation of the molecule, it may be necessary to conduct stability studies at lower temperatures such as 5°C. This is because the rate of degradation of a molecule can be affected by temperature, and lower temperatures can slow down the degradation process and extend the shelf life of the drug product.

Overall, it is important to conduct stability studies under different storage conditions to evaluate the effect of temperature on the stability of the drug product and to ensure that it remains safe, efficacious, and of high quality throughout its intended shelf life.

Freezing-Thawing:

It is important to conduct stability studies on frozen preparations when the literature recommends freezing or when the active ingredient degrades rapidly at ambient or refrigeration temperatures. When conducting a stability study on frozen preparations, it is crucial to maintain a consistent temperature of approximately -20°C±5°C throughout the study.

Regular temperature recording should be performed to ensure that the temperature remains within this range. This will help to prevent any fluctuations in temperature that could affect the stability of the frozen preparation and the active ingredient.

During the stability study, various parameters such as physical appearance, chemical stability, and potency of the active ingredient can be monitored over time. The results of the stability study will help to determine the shelf-life of the frozen preparation and the appropriate storage conditions for the product.

It is important to note that stability studies are a crucial part of the drug development process and are required by regulatory agencies to ensure the safety and efficacy of pharmaceutical products. Therefore, it is essential to follow established guidelines and protocols when conducting stability studies to ensure accurate and reliable results.

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Residual Moisture:

Stability testing in a climate chamber with a temperature of 25°C and a residual moisture level of 60% ± 5% is commonly used to meet the stability testing conditions recommended by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

This type of stability testing is important for determining the shelf life of pharmaceutical products and ensuring their quality and safety over time. By subjecting a drug product to specific environmental conditions, such as temperature and humidity, the pharmacist can evaluate its stability and determine its expiration date.

It's worth noting that stability testing conditions may vary depending on the specific requirements of a drug product. Other factors, such as pH and light exposure, may also need to be taken into consideration when conducting stability testing.

Light:

The use of day/night ambient light is a common recommendation when there is no available data from the literature regarding the potential photosensitivity of the active ingredient. This approach helps to minimize the potential impact of light on the drug product during stability testing.

However, if the active ingredient is known to be photosensitive, additional measures must be taken to protect the drug product during stability testing. This may involve conducting tests while the drug product is shielded from light using appropriate packaging and storage conditions.

For instance, suitable packaging, such as an amber bottle or opaque packaging, can help to protect the drug product from light exposure. Additionally, an opaque outer packaging can be used to further shield the drug product from light during storage and transport.

It's essential to consider the potential impact of light exposure during stability testing, as light can cause changes in the chemical structure of the active ingredient, leading to a decrease in the drug's potency or the formation of impurities that could compromise patient safety. Therefore, appropriate measures should be taken to ensure that the drug product is stable and safe for use throughout its shelf life.

Duration of Study:

It seems that the text you provided is incomplete and lacks context. However, I can still provide you with some general information about real-time studies, storage periods, and the ICH guidelines.

Real-time studies are an essential part of drug development, where the stability of a drug product is monitored over time under recommended storage conditions. These studies are conducted to ensure that the drug product remains safe, effective, and of high quality throughout its shelf-life.

The storage period for drug products is usually determined by the manufacturer, based on the stability data obtained from real-time studies. The storage period may vary depending on the nature of the drug product, storage conditions, and the intended use of the product.

The International Conference on Harmonisation (ICH) is a global organization that provides guidelines on drug development and registration. The ICH guidelines provide recommendations on various aspects of drug development, including stability testing.

Accelerated aging studies are often used to predict the long-term stability of a drug product by subjecting it to stress conditions that accelerate the degradation pathways. These studies can provide valuable information on the degradation pathways and the likely stability of the drug product under real-time storage conditions.

Pharmacists play a crucial role in ensuring the quality and safety of drug products by following the guidelines and protocols set forth by regulatory bodies such as the ICH. They work closely with other healthcare professionals to ensure that patients receive safe and effective treatments.

Sampling time point:

Subsequent to this, sampling time points are calculated with reference to the maximum planned duration. We recommend establishing a minimum of 5 sampling time points between the initial time T0 and the maximum duration. We propose sampling frequencies corresponding to about 1/24th, 1/12th, ¼, ½ and¾ of the maximum duration. These frequencies may be adjusted slightly to fit around a reasonable working schedule. 8)

Analysis to be performed:

An assay of the active ingredient and monitoring of the appearance of degradation products are performed systematically. The other analyses to be performed are determined according to the pharmaceutical dosage-form used for the

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stability study. In the case of sterile preparations, the physicochemical stability study may be supplemented by a microbiological stability study.

II. CONCLUSION :

Herbal products are widely used and produced in industrial numbers in both developing and developed nations. To ensure product quality, safety, and efficacy, the stability of these herbal medicines is of ut most importance. Manufacturers of herbal products are expected to use the required procedures and methods to attain and maintain the stability of their goods during production, storage, transit, and use. This will promote compliance, patient confidence in herbal products, and patient safety and product efficacy.

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