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Review About Herbal Based Semisolid Dosage Forms.

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ABSTRACT

Herbal-based semi solid dosage form has a wide spectrum applicability for the treatment of various skin disease. These has been become more global for medicinal and economical value and are made up of herbs, which are the topical dosage form used for therapeutic, protective or cosmetic function. From plants, parts of plants or extracts from plants that are used in health-care or in combating the disease. They contain one or more ingredients that are active dissolved or uniformly dispersed in a suitable base and suitable excipients. The emulsifiers such as viscosity increasing agents, antimicrobial agents, antioxidants, or stabilizing agents etc. Advantage of Topical dosage form includes avoidance of systemic toxicity and side effect. The well-known semisolid dosage form are cream, ointment, paste, gels, etc. The guidelines also includes classification, API, instruments and evaluation of semisolid dosage form.

Keywords: Excipients, Process, Manufacturing Machines, Quality Control Test.

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INTRODUCTION

Herbal semisolid constitute a significant proportion of pharmaceutical dosage forms. They serve as a carrier for drug that topically delivered by the way of skin, cornea, rectal, tissue, nasal mucosal, vagina, buccal tissue, urethral membrane , and external ear lining. Herbalism as a long tradition of use outside of conventional medicine. Clinical research show the value of herbal medicine in treating and preventing diseases. They contain one or more active more ingredient dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agent, anti-microbial agent, antioxidant and stabilizing agent.

Herbal medicines (HMs) have been defined as "preparations manufactured industrially consisting of active ingredient(s) which is/are purely and naturally original, not chemically altered plant substance(s), and is/are responsible for the overall therapeutic effect of the product".

Herbal preparations are made from herbal medicines such as whole plants, plant parts, algae, fungi, lichens, exudates, dry or fresh in their raw form, and vary from infusions, decoctions, wicking, distillation, etc. Extracted with the help of the process. Expression, fractionation, purification, concentration, fermentation.

RECENT STUDY

The development and mass production of chemically synthesized drugs over the past 100 years has revolutionized healthcare in most parts of the world. However, a large proportion of the population in developing countries still rely on traditional practices and herbal medicines for their primary care. In Africa, up to 90% and in India, 70% of the population depend on traditional medicine to help meet their health care needs. In China, traditional medicine accounts for approximately 40% of all health care provided, and more than 90% of general hospitals in China have traditional medicine units (WHO 2005). Further, a recent study indicated that more than 70% of the German population reported using "natural medicines" and that, for most of them, herbal medicinal products were the first choice in the treatment of minor diseases or disorders. The worldwide consumption of herbal medicines is enormous, so that, in terms of population exposure alone, it is essential to identify the risks associated with their use.

Types of Herbal-Based Semisolid Dosage Form

- Herbal Ointments,
- Herbal Paste,
- Herbal Cream,
- Herbal Gels,
- Herbal Jellies.

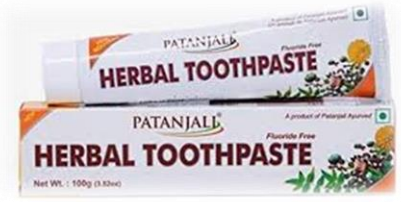
HERBAL OINTMENTS

Herbal Ointments are semisolid, greasy preparations for External application (Skin, Rectum or Nasal Mucosa). The base is usually anhydrous (hydrophobic) and immiscible with skin secretions. Herbal Ointments contains the plant fabrics either in the not often sifted or extracted from organized into the base. These should not be used for deep wounds and are comparably resistant when compared accompanying added liquid portion of drug or other consumable forms.

HERBAL PASTE

Herbal pastes may contain as much as 50 % powder dispersed in a fatty base . These pastes normally localize the action of irritant or staining materials. They are normally less greasy than ointments. Herbal

pastes may contain the herbal ingredient dissolved or dispersed in a base. The stability of an herbal paste depends on the type of base used as well as the nature of the herbal material incorporated.



HERBAL CREAMS

Herbal Creams are viscous semisolid emulsions that are mixtures of oil and water (hydrophilic). The materials which are used is either finely sifted form or incorporated as an extract. It also contain antimicrobial preservatives due to the presence of water in the base and may have a relatively shorter shelf life compared to ointments. The base is purely hydrophilic.

HERBAL GELS

Herbal Gels are semisolid dispersion systems, which may contain suspension of either small / large organic molecules, dispersed in a suitable liquid. Those are semi rigid structure of three-dimensional network of particle or macromolecules of the dispersed phase, and has a network of small separate particle, thus is considered a two-phase system. Single-phase gels have organic macro molecules distributed uniformly in a liquid so that no apparent boundaries are formed between the dispersed macromolecules and the liquid.

HERBAL JELLIES

Herbal Jellies are transparent or translucent, non-greasy semisolid dosage form. They are mainly used for mucous membrane for lubricating, antiseptic purpose. Jellies are also used for lubricating surgical gloves, catheters & rectal thermometers. Vaginal Jellies & contraceptive Jellies are also commonly used.

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Advantages Of Herbal Semisolid Dosage Forms

- Used in external route of administration.
- Side effect can be reduced.
- Local action and Site-specific action of drug.
- Patient those having difficulty on oral administration.

Disadvantages Of Herbal Semisolid Dosage Forms

- The base used in the preparations can be easily oxidized.
- May cause staining.
- Application with finger may cause contamination.
- May cause irritation or allergy to some patients.

Ideal Properties Of Herbal Based Semisolid Dosage Form

Physical Properties	Physiological Properties	Application Properties	Storage Properties
Smooth texture	Non irritating	Easily applicable	Not exceed 25℃
Elegant in appearance	Do not alter membrane	High aqueous washing ability	Stored in a well closed container
Non greasy and non straining	Miscible with skin secretion	----------	Not be allowed to freeze
Non hygroscopic	Low sensitization index	----------	----------

Methos Used In Herbal Based Semisolid Dosage Forms

Trituration Method (Ointments, Paste)

The required quantity of solid ingredient and base are weighed accurately. The weighed solid ingredient is powdered to make fine particle and triturated with the base taken` in small quantity. Trituration is done with a spatula on a plain slab to form a product having homogenous and uniformly distributed particles. The amount of base left over is added to consistent product to form a homogenous mixture. Further the liquid medicament is added to the uniform mixture.

Fusion Method (Ointments, Paste)

The solid ingredients are melted in decreasing order of their melting points. The ingredients with highest melting point is melted first followed by the other lower melting point ingredients. Then the active drug is slowly added, with the constant stirring into the mass formed above, till a homogeneous mixture of uniform consistency is obtained. Further if required the liquid ingredient is added to the melted bases in the melted base in the melted form with constant stirring and mixing well, the preparation should be filtered by the muslin cloth and then label and finally dispensed into a suitable container.

Levigation Method (Creams)

Through the use of water, lavigation process grinds an insoluble substance into a crushed fine powder. Thus, it is also known as 'wet grinding. This powder stays on the water, flowing through the apparatus as it serves as a murky liquid or paste. Then, the material is brought into join the blend.

Thermal Changes (Gels)

Solvated polymers (lipophilic colloids) are subjected to thermal changes causes gelatin. Many hydrogen former are more soluble in hot than cold water. If the temperature is reducing, the degree of hydration is reduced and gelatin occur. Cooling of a concentrated hot solution will produce a gel. Raising the temperature of the solution will disrupt the hydrogen bonding and reduced solubility, which will cause gelation.

Chemical Reaction (Gels)

The solute interacts chemically with the solvent to form gel.

Excipients Used In Herbal Based Semisolid Dosage Forms

The Common Excipients are,

Preservatives

Certain semisolid base are capable of tolerating microbial attack Since these bases have high water content, an anti microbial preservative is added in the ointment formulation to maintain their potency and integrity. The resist the microbial attack but because of their water content, it require an anti microbial preservative. Example are, Methyl paraben, Ethyl paraben, Propyl paraben. Benzoic acid, Methyl hydroxy benzoate.

Antioxidant

The oxygen is a highly reactive atom that is capable of becoming of potentially damaging molecule commonly known as a free radicals. The free radicals are capable of attacking the healthy cells of the body, causing them to loose their structure and functions. They act as a chain propagation step where they break the free radical chain reaction.

Eg: Butylated Hydroxyl Anisole (BHA), Butylated Hydroxy Toluene (BHT). Tocopherol (available naturally).

Emulsifying Bases

- Oil in Water Bases, The basic properties of these bases include their hydrous, water soluble, water absorbable, water washable in nature.
  Eg: acting as drug carrier or vehicle includes PEG ointment, Poly bases etc.
- Water in oil Emulsion Bases: These bases are hydrous, hydrophilic in nature, absorb Water, and cannot washed. Their thermal conductivity and occlusive property is low. Some of their properties are similar to that absorption bases.
  Eg: cold cream type, hydrous lanolin, rose water ointment, and hydro cream.

Jellying Agent

The jellying agents are, Tragacanth. Sodium alginate, Pectin, Starch, Gelatin.

Tragacanth

It is commonly used for the preparation of lubricating, medicated & contraceptive jellies. For lubricating jellies 2 to 3%. For dermatological vehicle about 5% For medica ted jellies 5%
Sodium Alginate

Those jellies are used as lubricants & for dermatological vehicle In lubricants 1.5 to 2% & for dermatological vehicle 5 to 10% sodium alginate used. In that type of jellies alcohol, propylene glycol or glycerin used as dispersing agents.

Pectin

Pectin is a very good gelling agent. Pectin used in various preparation of jellies including edible jellies. It is mainly used in dermatological jellies. Glycerin is used as humectant & dispersing agent Pectin jellies prepared with suitable preservatives.

Starch

Starch jellies prepared with combination of gelatin & glycerin. Starch glycerin jellies prepared by heating method or fusion method. Glycerin in large amounts e 30% may be act as preservative & humectant.

Gelatin

Gelatin soluble in hot water 2% gelatin produce jelly in a hot solution. Very stiff medicated jellies can be prepared by incorporating with 15% gelatin. Such jellies melted before use & after cooling to desired temperature it can be applied with brush on affected area.

Surfactants

Surfactant are added to form micelles in aqueous media. Due to hydrophilic functional groups, micelles can enhance the solubility of poor water-soluble drug In topical formulation 2-10% surfactant help in the formation of micro structure and improves the trans mucosal absorption.

Eg: Tween 60, Tween 80, Potassium oleate

Chelating Agent

The chelating agent prevent the oxidation of a product catalyse by traces of heavy metals. The chelating agent are form a complex with the heavy metal. This causes unavailability of the metal ions to catalyse the oxidation. Eg: EDTA (Ethylene diamine tetra acetic acid), Citric Acid. Tartaric Acid The EDTA in a buffer system avoid degradation of drug like Prednisolone and ascorbic acid.

Vehicles

Substance which are of little or no therapeutic value but which are added to the formulation in order to :

- Help the production.
- Maintain physiologically stability.
- Improve patient acceptability.

Polymer

In general, formulators use polymers to increase viscosity to improve suspension/retention characteristics. Most polymers used in commercial pharmaceutical production can be divided into three classes:

- Fermented (e.g. Xanthan gum)
- Synthetic (e.g. hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), carbomer

- Natural (e.g. acacia, starch).

Humectants

Humectants are substances that attract water from the air or from deeper in the skin. They come in three main forms: natural or unchanged, naturally derived, and synthetic. You can find humectants mainly in skin care and hair care products, but many industries use them.

Equipments Used In The Semisolid Dosage Forms

Triple Roller Mill

A three roll mill has three horizontally positioned rollers. Each roller rotates in an opposite direction from the adjacent roller with a tiny gap between them, creating tremendous shear force that can finely disperse, mix, refine or homogenize viscous materials. Three roll mill is a dispersing tool, not generally a size reduction tool. Fine particles tend to agglomerate and a three roll mill applies powerful shear force to break apart those agglomerations. As a result, the final fineness depends on the original particle size of the dry ingredients.

Three Roll Mill Operation

STEP 1: Make sure end plates and receiving apron is securely installed.
STEP 2: Adjust roller gaps to desired level (usually between 20 and 150 microns) and lock hand wheels in place.
STEP 3: Starting from a slower speed, push the start button to get the rollers running.
STEP 4: Feed materials through the gap between the slow roller and the middle roller.
STEP 5: Collect the material from the receiving apron.
STEP 6: Use STOP button the stop the machine as needed.
STEP 7: Run the material 2-3 times till the desired fineness is achieved.

Colloid Mill

Colloid mill is a machine that is used to reduce the particle size of a solid in suspension in a liquid or to reduce the droplet size in emulsions. When a liquid is suspended in another liquid, meaning they are immiscible, this machine is used to alternatively to reduce the size of this droplet. A high level of hydraulic shear stress is applied on the fluid which results in disrupting and breaking down the structure.

Principle

Works on the principle of ROTOR AND STATOR, Size reduction is affected due to shearing Rotor become high speed and high level of hydraulic shear applied. Shear rate leads to smaller droplets. Particle size done by modifying the gap between Rotor and Stator. Drain pipe removes the final product.

Parts

To feed the material hopper is used which are attached to the rotor and Stator assembly Rotor and Stator which are made of stainless steel may be rough or finish surface is used for Shearing the mixture, Motor assembly to rotate. A discharge point for outlets the mixture and a auto circular tube.

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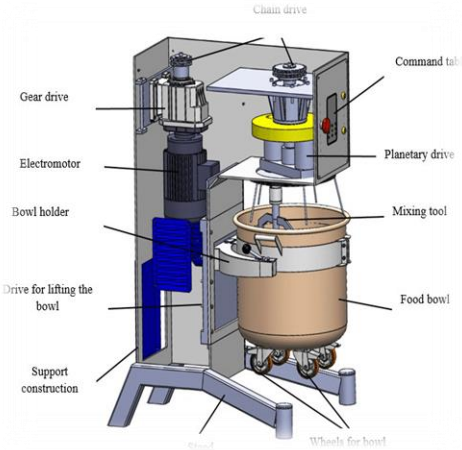
Mechanism

The material is placed into the mill though the inlet hopper. It is then passed through the narrow gap between the rotor having and stator and thus reduced the fine particle size. By the help of pulverization. . Then it will come to the auto circular tube until we allow it to came out from the discharge port The rotor speed is 3000 to 20000rpm and can produce particle size of 1.

Planetary Mixer

Planetary mixers are one of the most widely used mixers in the pharmaceutical industry In the pharmaceutical industry, the planetary mixer is often used for basic operations of mixing. blending, and low-shear granulation This machine is also used in other industries like cosmetics and personal care products, food, glass, cements. ceramics, metal industry etc.The Planetary Mixer have two blades which rotate on their own axes, while they orbit the mix vessel on a common axis The blades continuously advance along the periphery of the vessel: removing material from the vessel wall and transporting it fix the interior These mixers are ideal for mixing and kneading viscous pastes or putty-like materials.



Quality Control Test For Herbal Based Semisolid Dosage Form

Evaluation Of Ointments

Drug Content

In the minimum fill test. Select any 10 filled containers Weigh the required amount of ointment and Medicament is extracted in a suitable solvent Drug Content is determined by suitable analytical technique. Results should be with in labeled quantity.

Release Rate Of Medicated From Base

The Release rate of medicament from base is determined by Two in vitro techniques they are Agar cup plate method, Diffusion method Agar cup plate method.

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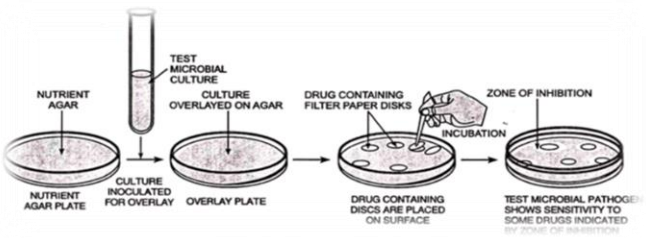
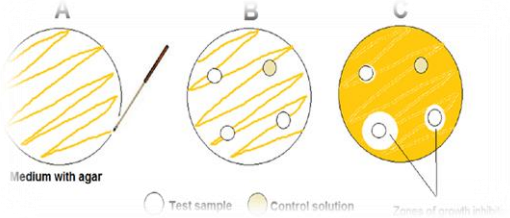
Agar Cup Plate Method

To asses the rate release of medicament from the small amount of ointment can be placed on the surface of nutrient agar containing in the petri dish or alternatively in a small cup cut in agar surfaces. If the medicament is bactericidal the agar plate is previously seeded with a suitable organisim like s.aureus after a suitable period of incubation, the zone of inhibition is measured and correlated with rate release of medicament.



Diffusion Method

Diffusion method is Used to find the release rate of any type of medicament from the base A parchment membrane is tied at one end of glass tube. Ointment is filled in the tube, properly spread on the membrane. Tube is dipped in the distilled water maintained at 37+10°C. Samples are withdrawn after a specified period of time. Samples are immediately replaced with fresh distilled water.



Irritant Effect

Test is performed on skin and eyes of rabbit or human skin. Ointment is injected in to thigh muscles and under abdominal skin in rats. Results are observed daily for a week. Irritant effect of dermatological preparation is shown as lesions on cornea, iris and conjunctiva.

Evaluation Of Paste

Abrasiveness

They measure the amount of solid medicament as per the unit of the paste.

Particle Size

This can be determined by microscopic study of particle.

Rheology

Rheology are viscosity should remain constant. As there products are normally non newtonian in nature, the viscosity can be measured using viscometer are used for such liquid.

Evaluation Of Cream

Sensitivity

As a various type of ingredient are used with occasional use of antiseptic hormone etc. There is a possibility of sensitization or photosensitization of skin. This test is normally done by patch test on and can be either open or occlusive. The test sample is applied along with standard market product at different place and effect is compared after time period.

Consistency Of Preparation

Consistency of preparation is determined by sliding a glass plate over the product by means of a pulley Product is spread evenly on another glass plate fixed on a wooden block weight are added to the pan so that sliding of the movable glass plate is obtained. Ointment which require more weight to allow the plate to slide over have high consistency or vice versa.

Drug Content

Minimum fill test. Select any 10 filled containers. Weigh the required amount of ointment and Medicament is extracted in a suitable solvent. Drug Content is determined by suitable analytical technique Results should be with in labelled quantity.

Evaluation Of Gels

Drug Content

1 gm of gel was accurately weighed in 50 ml of volumetric flask to which 20 ml purified water was added with continuous shaking Volume was adjusted with mixture of 10% methanol in water Absorbance of solution with the blank was measured at 360nm using UV-Spectrophotometer.

Spreadability

A modified apparatus consisting of two glass slide containing gel in between with the lower slide fixed to wooden plate and the upper one attached to a balance by a hook was used to determine spreadability.

Viscosity

Brookfield viscometer is used for determination of viscosity gel were filled in jar and spindle was lowered perpendicularly taking are that spindle do not touch bottom of the jar. The spindle was rotated in the gel at increasing shear rates 0.5, 2.5, and 5 rpm. At each speed, the corresponding dial reading was noted.

Evaluation Of Jellies

Physical Evaluation

The medicated jelly can be examined physically for appearance like clarity, texture, transparency, consistency.

Stickiness And Grittiness

Texture of the medicated jelly in terms of stickiness and grittiness can be determined by mildly rubbing the jelly between fingers.

Spreadability

2.5g jelly should be placed in between 2 glass slides and compressed to proper thickness by keeping 1000g weight for 5 min. The time in seconds needed to separate 2 slides were taken. Less time interval to cover the distance of 7.5cm shown better spread ability.

$$S = W * L/T$$

where,

S = spreadability W = weight tied to upper slide
L = length of glass slide T = time required to separate 2 slides.

Packaging Of Semisolid Dosage Form

Packaging is the process by which the pharmaceuticals are suitably placed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. The ideal container or package should:

Protect the contents from the following environmental hazards:

- Light – protect the contents from light.
- Temperature – be capable of withstanding extremes of temperature.
- Moisture – be capable of withstanding extremes of humidity.
- Particles – protect from particulate contamination.
- Microorganisms – protect from microbial contamination.

Protects the content from the following mechanical hazards

- Vibration – Usually due to transportation.
- Compression – this usually includes pressure applied during stacking.
- Shock – such as impact, drops or rapid retardation.
- Puncture – penetration from sharp objects or during handling operations.
- Abrasion – this may create electrostatic effects.

They must not add or permit loss to its contents:

- Protect the contents from both loss and gain of water.
- Protect the contents from loss of volatile materials.
- Must not shed particles into the contents.
- Must not leach anything to the contents.

Storage Conditions Of Herbal Semisolid Preparations

- If rapid analysis methods are not developed. It is common practice to store the semi-solid material until a specified quality control test has been completed prior to packaging in a suitable container.
- Container: - tube, jar or single-dose package.
- The product is considered to be in the manufacturing process until it is packaged.
- The active ingredient in the cream or ointment may react with the storage container unless high-strength stainless steel is used for bulk storage.
- Evaporation of water from the cream must be slowed down: This can be effectively achieved by placing non-reactive plastic sheeting in direct contact with the cream and also by covering the storage container with a tight fitting stainless steel [1-19].

CONCLUSION

The main advantages of Herbal semi-solid dosage forms are non-greasy, as they consist of water-washable bases, ease of application, rapid formulation and the ability to deliver a wide range of drug molecules locally. Currently, more efforts have been made to achieve controlled release formulations using various carrier systems that have eliminated the cosmetically unfavourable properties of conventional semi-solid dosage forms. When developing a semsolid dosage form, the appropriate choice of excipient and safety assessment are important. Pharmaceutical factors are stability, solvent properties, emulsifying properties. In addition, patient acceptability is much better than other drug delivery methods due to its non-invasiveness.

REFERENCES

[1] Idson B. Lazarus j. Semisolids in the Theory and Practice of Industial Pharmacy. In Lachman L, Lieberman HA, Kang JL editors; Varghese Publishing House, Bombay, India: pp. 534-563 1991.
[2] Block LH. Medicated Applications. In Gennaro AR: Remington: The Science and Practise of Pharmacy. Mack Publishing Company, Easton, Pennsylvania: pp. 1577-1597.,1995

[3] https://images.app.goo.gl/vi9v3iBx6YzpR948
[4] Nwoko, V.E. Semi solid dosage forms manufacturing: tools, critical process parameters, strategies, optimization and validation. Sch Acad J Pharm, 3(2), pp:153-161,2014.
[5] https://www.slideshare.net/laithalasadi/semi-solid-dosage-form-68119310
[6] Kaur, L.P. Asian Journal Of Biomedical And Pharmaceutical Science 2013;3(17):1.
[7] https://www.slideshare.net/rababambreen1/semisolid-dosage-form
[8] Patel, H., Parmar, S. and Patel, B. A comprehensive review on Quality by Design (QbD) in pharmaceutical development, 4, p 5,2013
[9] https://www.scribd.com/doc/40268318/Semi-Solid-Mixers
[10] https://www.slideshare.net/docmanol 5/semi-solid-dosage-forms
[11] https://www.slideshare.net/pkcchhajer/semi-solid-dosage-forms-44039499
[12] https://www.researchgate.net › 319...
[13] (PDF) Dosage forms of herbal medicinal products and their stability ...slideshare.net
[14] https://www.slideshare.net › semiso...Semisolid dosage forms – SlideShare
[15] https://www.jpsr.pharmainfo.in › ...PDF
[16] Pharmaceutical Jellies: A novel way of drug delivery. pharmainfo.in
[17] https://www.jpsr.pharmainfo.in › ...PDF
[18] Pharmaceutical Jellies: A novel way of drug delivery ondrugdelivery.com
[19] https://www.ondrugdelivery.com ›...Excipient Choices and Why They Matter in Topical Formulations