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Review Article

Study of Natural Excipients in Semi-Solid Dosage Forms

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Abstract

A significant proportion of pharmaceutical dosage forms are semi solid preparations. They serve as carriers f drugs that are topically delivered by way of the skin, cornea, rectal tissue, nasal mucosa, vagina, buccal tissu urethral membrane, and external ear lining. This data collection's goal is to give readers a comprehensi understanding of the different tools, tactics, crucial process variables, and production and validation procedur processes specific to semisolid dosage forms.

Key Words: semi-solid dosage forms; excipients; natural excipients

Introduction

Typically, topical semisolid dose forms are in the shape of pastes, ointments, gels, or creams. The ease of use, quick formulation, and capacity to topically administer a broad range of drug molecules are all benefits of a semisolid dosage form. There are many different dose forms for semisolids, and each has special qualities. In addition to any appropriate excipients, such as emulsifiers, viscosity-increasing agents, antimicrobial agents, antioxidants, or stabilizing agents, they comprise one or more active substances that have been dissolved or evenly distributed in an appropriate base.

Figure 1: Semi solid dosage forms

Advantages for semi solid dosage forms:

- It is used externally
- Probability of side effect can be reduced
- Local action
- First pass gut and hepatic metabolism is avoided.
- Patient compliance is increased, the drug termination is problematic cases is facilitated as compared with other routes of drug administration [1]

Formulation	Description
Ointments	Ointments are homogenous, semi-solid preparations intended for external application to the skin or mucous membrane.
Creams	Creams are homogeneous, semi-solid preparations consisting of opaque emulsion systems.
Gels	Gels are usually homogeneous, clear, semi-solid preparations consisting of a liquid phase within a three-dimensional polymeric matrix with physical or sometimes chemical cross-linkage by means of suitable gelling agents.
Pastes	Pastes are homogeneous, semi-solid preparations containing high concentrations of insoluble powdered substances (usually not less than 20%) dispersed in a suitable base
Poultice	A poultice is an ancient form of topical medication also known as a cataplasm. It is a soft mass of vegetable constituents or clay, usually heated before application.[2]

Table 1: Types of semi-solid dosage forms

Ointment: Ointments are homogenous, semi-solid preparations intended for external application to the skin or mucous membrane. They are used as emollients or for the application of active ingredients to the skin for protective, therapeutic, or prophylactic purpose and where a degree of occlusion is desired.

Advantage of ointments as a dosage forms:

- Inexpensive
- Nonreactive
- Non-irritating
- Good emollient, protective, and occlusive properties
- Not water-washable so they stay on the skin and keep incorporated medications in contact with the skin[2]

Emulsifying agent	Cotton seed oil, Paraffin wax, Beeswax, Palm oil
Humectants	Propanediol, vegetable glycerine, honey, marine collagen
Preservatives	Clove oil, Neem oil, Cumin seeds, Cayenne pepper
Antioxidants	Peppermint, Rosemary, Cinnamon, Saffron
Oleaginous bases	Castor oil, Lanolin, Mineral oil, Sunflower oil [3]

Table 2: Excipients used in ointments

OINTMENT BASES: The vehicle or carrier of an ointment is known as ointment base. The choice of ointment base depends upon the nature of medicament, stability of ointment and clinical indication of the ointment. [4]

Property	Oleaginous compounds	Oleaginous bases + w/o surfactant	Oleaginous base + water	Polyethylene glycol
Water content	Anhydrous	Anhydrous	hydrous	Anhydrous hydrous
Affinity for water	Hydrophobic	Hydrophilic	Hydrophilic	Hydrophilic
Spread ability	Difficult	Difficult	Easy	Moderate- easy
Washability	Non washable	Non washable	washable	washable
Stability	Oils poor, hydrocarbon better	Oils poor, hydrocarbon better	Unstable especially alkali soap and natural colloids	Stable

Table 3: Properties of different ointment bases

Ideal properties of Ointment bases

- Chemically and physically stable under normal conditions of use and storage
- Nonreactive and compatible with a wide variety of drugs and auxiliary agents
- Free from objectionable odor
- Nontoxic, non-sensitizing, and nonirritating
- Aesthetically appealing, easy to apply, and nongreasy
- Remains in contact with the skin until removal is desired, then is removed easily [5].

Excipient	BS	Family	Synonym	Use	Formulation
Castor oil	It is obtained from seeds of Ricinus communis	Euphorbiaceae	Ricinoleic acid	Ointment base	Topical ointments
Sunflower oil	It is obtained from fruits and seeds of Helianthus annus	Compositae	Helianthus annus oil Oleum helianthin	Ointment base	Skin creams Lotions
Mineral oil	It is a mixture of refined liquid saturated aliphatic and cyclic hydrocarbons obtained from petroleum	_	Heavy mineral oil, Liquid petroleum	Ointment base	Opthalmic formulations, Transdermal contraceptive patches, Suppositories
Lanolin	It is obtained from wool of sheep, Ovis Aries linn	Bovidae	Refined wool fat	Ointment base	Creams, Ointments, Suppositories [6]

Table 5: Details of various natural oils as excipients in semi-solid dosage forms

EMULSIFYING AGENT: Emulsions are liquid disperse systems consisting of two immiscible phases, one of which is dispersed as globules in the other liquid phase [7]. The two phases of emulsions are stabilized by the presence of an emulsifier. The droplet diameter of the dispersed phase extends from about 0.1 to 10 µM, although particle diameters as small as 0.01 µM and as large as 100 µM are not uncommon. The consistency of emulsions ranges from that of a liquid (e.g., fat emulsions) to a semisolid (e.g., ointments and creams]

Ideal properties of natural emulsifying agents:

- Emulsions exhibit all of the properties of a colloidal solution, including Brownian movement, Tyndall effect, and electrophoresis.
- The addition of electrolytes containing polyvalent metal ions coagulates the globules, demonstrating their negative charge.
- In emulsions, the size of the dispersed particles is bigger than in sols. It has a range of 1000 to 10,000 Ă. The size, on the other hand, is less than that of particles in suspensions

Excipient	BS	Family	Synonym	Use	Formulation
Soybean oil	It is extracted from seeds of soybean plant(Glycine max)	Fabaceae	Soy oil	Emulsifying agent	Creams
Paraffin wax	Paraffin wax is manufactured by distillation of crude petroleum or shale oil.		Paraffin durum	Emulsifying agent	ointments
Beeswax	Bees wax is obtained from the honey comb of the bee	Apidae.	Cagesoft, Dynasanp60	Emulsifying agent	Ointments
Palm oil	the oil obtained from the pulp of the fruit of the oil palm Elaeis guineensis jacq	Aceraceae.	Cage soft Dynasanp60	Emulsifying agent	Creams Ointments [8]

Table 6: Details of various natural emulsifying agents as excipients in semi-solid dosage forms

HUMECTANT: these are an important group of cosmetic ingredients and will be found in most skin care products that contain an aqueous phase. Humectants moisturise the skin in a unique way. They attract water to the skin.[9]

Ideal properties of natural humectants:

- Good odour and taste
- Non-corrosive to packaging material
- Non-toxic, non-irritant
- compatible with other materials
- Not solidify or crystallize at normal condition

Excipient	BS	Family	Synonym	Use	Formulation
Marine collagen	Derived from fish collagen peptides	-	Fish collagen	Humectant	Creams, serums
Honey	Produced by our little bee friends	Apidae.	Madhu	Humectant	Ointments, Creams, Syrups
Vegetable glycerine	Derived from plant sources, glycerine is a thick sweet, sticky liquid	-	Glycerol	Humectant	Ointments
Propanediol	Derived from cane sugar	-	-	Humectant	Lotions, Cleansers [10]

Table 7: Details of various natural humactants as excipients in semi-solid dosage forms

PRESERVATIVES: Preservatives are usually used to minimize the shelf life of several food products and pharmaceuticals. Preservatives are vital to avoid the alteration and degradation of microorganisms during storage. Particularly in those with greater water content [11]

Ideal properties of natural Preservatives:

- It should not be irritant.
- To maintain product consistency.
- To maintain palatability and wholesomeness.
- It should not be toxic.
- It should be stable (physically and chemically).
- It should be compatible with all other ingredients
- It should be acting as good antimicrobial agent
- It should be potent in action.
- It should have higher shelf life

Excipient	BS	Family	Synonym	Use	Formulation
Lemon oil	Extracted from the peel of citrus limon fruit	Rutaceae	Citrus limon peel oil	Preservative	Shampoos Pastes
Neem oil	Fruits of azadirachta Indica	Meliaceae	Margosa oil	Preservative	Shampoos, Creams
Cumin seeds	Seeds of Cuminum cyminum	Apiaceae	Nigella	Preservative	Suppositories
Cayenne pepper	Fruits of piper nigrum	piperaceae	Chilli pepper	Preservative	Topical ointments Creams [12]

Table 8: Details of various natural preservatives as excipients in semi-solid dosage forms

ANTIOXIDANTS: Antioxidants are substances which counteract free radicals and prevent the damage caused by them. These can greatly reduce the adverse damage due to oxidants by crumbling them before they react with biologic targets, preventing chain reactions or preventing the activation of oxygen to highly reactive products

- **Ideal properties of natural Antioxidants:**
- It should be stable
- It should be effective in low concentration

- It should be compatible
- It should be non-toxic [13

Excipient	BS	Family	Synonym	Use	Formulation
Catechin	It is a flavonoid antioxidant found in many plants, fruits, and vegetables	-	Flavanol	Antioxidant	Creams
Wheat bran	Its comes from the outer layers of the wheat kerneal	Gramineae	Cereal fiber Dietary fiber	Antioxidant	Nano emulsions [14]
Saffron	Saffron consists of the dried stigma of the flowers of the crocus bulb, crocus sativus		Kesar, Jafran	anti-oxidant.	Creams lotions

Table 9: Details of various natural humactants as excipients in semi-solid dosage forms

Creams:

Creams consist of opaque emulsion systems and are semi-solid, homogenous formulations. The kind of emulsion—water-in-oil (w/o) or oil-in-water (o/w)—as well as the makeup of the solids in the internal phase determine their consistency and rheological characteristics. Creams are designed to be applied to the skin or specific mucous membranes for preventive, therapeutic, or protective reasons, particularly in situations where an occlusive effect is not required. Topical medicines that can be applied to the skin are called creams. "Viscose liquid or semi-solid emulsions of either the oil-in-water or water-in-oil type" dosage forms, with varying oil and water contents, are referred to as creams. [15]

Ideal Properties Of Creams

- Inert
- Stable
- Smooth
- Compatible with the skin
- Non-irritating
- Should release the incorporated medicaments readily.

Types of skin creams:

They are separated into two categories: An **oil-in-water** (O/W) emulsion is one in which the oil is distributed as droplets throughout the aqueous phase, whereas oil-in-water (O/W) creams are made up of tiny oil droplets distributed in a continuous phase. Creams known as **water-in-oil** (W/O) are made up of tiny water droplets scattered across an oily layer. The emulsion is of the water-in-oil (W/O) type when the dispersed phase is water and the dispersion medium is oil.

Cream types based on its purpose, unique qualities, and emulsion type:

- Make-up cream (o/w emulsion): a) Vanishing creams. b) Foundation creams.
- Cleansing lotion (without emulsion), cleansing milk, and cleansing cream
- Winter cream (without emulsion): a) Moisturising or cold cream.
- General and all-purpose creams.
- Massage and night creams.
- Skin protective cream.
- Hand and body creams.[16]

Thickening agent	Agar, Guar Gum, Xanthan Gum, Carrageenan
Emulsifying agent	Cotton seed oil, Paraffin wax, Beeswax, Palm oil
Preservatives	Clove oil, Neem oil, Tea tree oil, Ginger oil
Antioxidants	Peppermint, Rosemary, Cinnamon, Saffron

Table 10: Excipints Used In Creams:

Thickening agent:

A thickening agent, sometimes known as a thickener, is a material that can raise a liquid's viscosity without significantly altering its other characteristics. In addition to being used in paints, pigments, explosives, and cosmetics, edible thickeners are frequently used to thicken sauces, soups, and puddings without changing their flavour. Additionally, thickeners can enhance the suspension of other ingredients or emulsions, increasing the product's stability.

Ideal properties of natural thickening agents:

It should have proper texture

Maintain consistencTemperature [17]

Excipient	BS	Family	Synonym	Use	Formulation
Agar	Agar is mainly extracted from species of Gelidium amansii	Gelidaceae	Agar-agar, agar gum, gelidium-amansii	Thickening agent	Suppositories
Guar gum	Guar gum is obtained from the endosperm of the seeds of the guar plant	Leguminosae	Cyamopsis tetragonoloba gum, galactose gum, guaran	Thickening agent	Gels Opthalmic preparations
Xanthan gum	Xanthan gum is obtained from the bacteria Xanthomonas campestris	Pseudomonadaceae	corn sugar gum.	Thickening agent	oral gels Topical preparations
Carrageenan	Carrageenan as the hydrocolloid obtained by extraction with water or aqueous alkali	Rhodophyceae	Capsules	Thickening agent	Topical products

Table 11: Details of various natural thickening agent as excipients in semi-solid dosage forms

Marketed formulations

Formulation	Company[Brand]	Dosage form	Excipient used
 Kumkumadi glowing cream	Khadi natural	Semi solid dosage form	Saffron
 Vegan lipsticks	Blush-Bee	Semi solid dosage form	Cochineal
 Lanolin wax	Lodha petro	Semi solid dosage form	Lanolin
 Herbal lotions	Baidyanath	Semi solid dosage form	Mineral oil
 Mustela Hydrating cream	Expanscience laboratories	Semi solid dosage form	Sunflower oil
 Locust bean gun ceratop lotion	Labh additives	Semi solid dosage form	Ceratonia

Conclusion:

Pharmaceutical excipients derived from natural sources have attracted a great attention in developing convectional dosage forms and novel drug delivery systems. The use of natural excipients is steadily increasing day by day due to the side effects of synthetic excipients. Hence natural excipients are being preferred over synthetic as they are cheap, biodegradable and enhance the bioavailability, stability, safety, efficacy and patient compliance. Therefore, there is going to be a great interest in natural excipients to obtain a better dosage form.

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