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Review–Formulation Development of Semi-Solid Dosage Form

Shubham Pandey[1] Sujeet Pratap Singh[2], Dr. Tarkeshwar P. Shukla[3]
[1, 2, 3,] SCPM College of Pharmacy, Gonda

Abstract: Semi-solid dosage forms are generally found in medicines for all types of patients. Though, they have specific advantages, along with fast efficacy due to the devoid of dissolution time and quick absorption in the skin surface. Semi-solid formulations have been broadly used in pharmacy due to their high dosing adjustability, easy use off, and rapid onset of action.

Keywords: Semi-solid dosage forms, Gels, Ointment, Cream

Introduction:

Semi-solid dosage forms are a pharmaceutical preparation in which one or more active ingredients dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agents, anti microbial agents, antioxidants, or stabilizing agents etc. Semi solids are the topical dosage form used for the therapeutic, protective or cosmetic function. They may be applied to the skin, or used nasally, vaginally, or rectally.

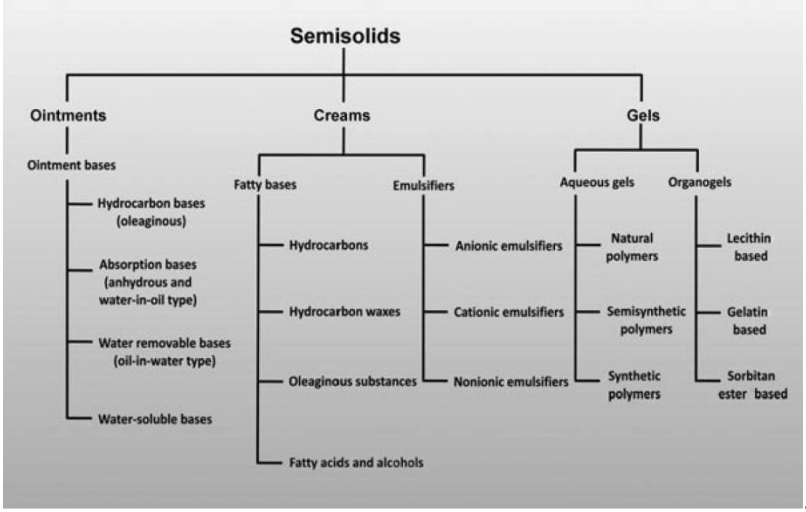
It can be administered by –Topically

Advantage of Semi-solid dosage form

- Probability of side effect can be reduce
- First pass gut and hepatic metabolism is avoided.
- Local action and Site specific action of drug on affected area.
- Convenient for unconscious patient or patient having difficulty on oral administration.
- Suitable dosage form for bitter drugs.
- More stable than liquid dosage form.

Classification

On the basis of viscosity they are classified into different types-



PREPARATION OF SEMISOLIDS DOSAGE FORMS INGREDIENTS USED IN PREPARATION:

• Bases • Preservative • Humectants • Antioxidants • Emulsifier • Gelling agent • Permeation enhancer • Buffers

1. BASES: It is one of the most important ingredients used in formulation of semisolid dosage form. Ointment bases do not merely act as the carriers of the medicaments, but they also control the extent of absorption of medicaments incorporated in them.

IDEAL PROPERTIES OF A BASE:

- They should be Inert, non-irritating and non-sensitizing.
- Compatible with skin pH and the drug.
- Good solvent and/or emulsifying agent.
- Emollient, protective, non-greasy and easily removable.
- Release medicament readily at the site of application.
- Pharmaceutically elegant and possess good stability

CLASSIFICATION OF BASES: Ointments bases are classified by the USP into four general groups:

- Hydrocarbon bases (oleaginous bases) (Petrolatum , Paraffin, Lanolin etc.)
- Absorption bases (cold cream, anhydrous lanolin …) C- water-removable bases (oil in water) D-water-soluble bases (polyethylene glycol)

ANTIOXIDANTS : Oxygen is a highly reactive atom that is capable of becoming part of potentially damaging molecules commonly called "free radicals." Free radicals are capable of attacking the healthy cells of the body, causing them to lose their structure and function. To prevent this antioxidants are added. E.g. Butylated hydroxy anisole, Butylated hydroxy toluene

PERMEATION ENHANCERS : Skin can act as a barrier. With the introduction of various penetration enhancers, penetration of the drug through the skin can be improved. Example- Oleic acid.

EMULSIFIER : An emulsifier (emulgent) is a substance that stabilizes an emulsion by increasing its kinetic stability. - Must reduce surface tension for proper emulsification. - Prevents coalescence. - Ability to increase the viscosity at low concentration.

Emulsifying agents - Sodium lauryl sulfate :O/W emulsion - Sodium stearate and calcium stearate. - Glyceryl monostearate: weak W/O emulsifying agents and used as stabilization agents and emollient in the O/W emulsion.

HUMECTANT: A humectant is a hygroscopic substance Humectants are used to increase the solubility of the active ingredient to elevate its skin penetration. It elevates the hydration of the skin. BUFFERS: Buffers are added for various purposes such as Compatibility with skin. - Drug solubility. - Drug stability. - Influence ionization of drug. Skin, due to its weak acidic nature, tolerates weak acidic preparations.

Antimicrobial preservatives -To inhibit the growth of contaminating microorganisms, so require the addition of chemical antimicrobial preservatives to the formulation -E.G. para-hydroxybenzoates (parabens), phenols, benzoic acid, sorbic acid, quaternary ammonium salts and other compound.

Ointments - Ointments are homogenous, translucent, viscous semi-solid preparations, most commonly a greasy, thick oil (oil 80% - water 20%) intended for external application to the skin or mucous membrane. They are used as: - Emollients - Protective - Therapeutic - Prophylactic purpose

Classification of ointments

A- Epidermic ointments - These ointments are intended to produce their action on the surface of the skin and produce local effect,they are not absorbed. • They acts as protectives, antiseptics and parasiticides.

B- Endodermic ointments - These ointments are intended to release the medicaments that penetrate into the skin. They are partially absorbed and acts as emollients, stimulants and local irritants.

C- Diadermic ointments - These ointments are intended to release the medicaments that pass through the skin and produce systemic effects.

Evaluation of ointments

Penetration -Weighed quantities of the ointments are rubbed over definite areas of the skin for a given length of time. Thereafter the unabsorbed ointment is collected from the skin and weighed. The difference between the two weights roughly represents the amount absorbed.

Creams: Creams are homogeneous, semi-solid preparations consisting of opaque emulsion contains lipophilic emulsifying agent . Their consistency depend on the type of emulsion, either water-in-oil (w/o) or oil-in – water (o/w), and on the nature of the solids in the internal phase. Creams are intended for the application to the skin or certain mucous membranes for: - Protective - Therapeutic - prophylactic purpose

Classification of creams

Creams containing microspheres (VIT. A CREAM 200-250 micron) Lamellar faced creams (liquid paraffin in water emulsion) Cream containing liquid nanoparticles (a w/o cream , more occlusive)

Preparation of creams Steps - Preparation of oil phase :flack/powder ingredient are dispersed in mineral oil or silicone oil) heating may required for melting - Hydration of aqueous phase: emulsifiers, stabilizer, thickener are dispersed in water heating may required for hydrating - Forming the emulsion: two phases are blended under vigorous agitation - Dispersion of active ingredient

Evaluation of creams

A- Rheology: The rheology or viscosity should remain constant. Rheologic measurements are utilized to characterize the ease of pouring from a bottle, squeezing from a tube or container - maintaining product shape in a jar or after extrusion, rubbing the product onto the skin . The viscosity can be measured using viscometers used for such liquids.

B- Sensitivity: As various types of ingredients are used with occasional use of antiseptic, hormones. etc., there is a possibility of sensitization or photosensitization of the skin. This should be tested before hand. This test is normally done by patch test on skin and can be either open or occlusive. The test sample is applied along with a standard market product at different places and effect is compared after a period of time.

Gels: Gels are homogeneous, clear, semisolid systems consisting of dispersions of small or large molecules in an aqueous liquid vehicle rendered jellylike by the addition of a gelling agent. Gels are aqueous colloidal suspensions of the hydrated forms of insoluble medicament, used for medication and lubrication.

Gelling agents : Among the gelling agents used - Synthetic macromolecules, such as carbomer 934 - Cellulose derivatives, such as carboxymethylcellulose or hydroxypropyl methylcellulose - Natural gums, such as tragacanth

Evaluation of gels - Drug content -1gm of gel was accurately weighed in a 50ml of volumetric flask to which 20ml purified water was added with continuous shaking. Volume was adjusted with a mixture of 10% methanol in water. Absorbance of the solution with the blank was measured at 360nm using UV-spectrophotometer. - Measurement of pH -The pH of gels were determined by digital pH meter. One gram of gel was dissolved in 100ml of distilled water and stored at 4°C for two hours.

Conclusion:

The formulation development studies of semi-solid dosage forms along with the pre-formulation studies include the various semi-solid formulation, research & the S.O.P handling. These are the important parameter of the pharmaceutical industries without this pharmaceutical industries does not conduct properly and the quality efficiency. This article may help to know about various types of liquid dosage with their preparation. New problems arise during development and it cannot be solve until required efforts with knowledge not met.

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