

OINTMENTS, PASTES AND JELLIES

A. Ointment

1. Traditionally the term ointment has been used for

(i) the general class name for all external use

semisolids and

(ii) the subclass, oleaginous semisolids. For example, defines ointments very generally as "semisolid preparations intended for external application to the skin or mucous membranes". However, pharmaceutical manufacturers use the word ointment more specifically to indicate that a drug is incorporated into an oleaginous ointment base; for example, the name Hydrocortisone Ointment means that hydrocortisone is incorporated into an oil-type semisolid base.

2. Under the proposed nomenclature, this situation would be clarified; the term semisolid would be used for naming the general class, and the term ointment would be redefined more narrowly as "a viscous oleaginous or polymeric semisolid dosage form," which is consistent with current usage by the pharmaceutical industry.

3. According to the USP Chapter there are four general classes of ointment (i.e., semisolid) bases.

Absorption bases

- c. Water-removable
- d. Water-soluble

B. Cream

Although it states that creams are "semisolid dosage forms containing one or more drug substances dissolved or dispersed in a suitable base," it then discusses the evolution of this term to include or exclude certain types of semisolid emulsions and aqueous microcrystalline dispersions.

2. The proposed new nomenclature both simplifies and clarifies the situation by defining a cream as "a dosage form comprising a viscous semisolid emulsion." Under this definition, creams would fall into two of the four general ointment base classes listed earlier: both water-containing absorption bases and water-removable bases.

C. Paste

1. As with creams, pastes meet the general definition of an ointment. They are defined as "semisolid dosage forms that contain one or more drug substances

intended for topical application." Then, to more clearly distinguish a paste from other topical semisolids. One group consists of very stiff ointments with a high concentration of solid particles in an oleaginous base: Zinc Oxide Paste USP is an example of this group. The other subclass is also very thick but has a single aqueous phase with a high polymer content: Carboxymethylcellulose Sodium Paste is an example of this group.

2. The proposed new nomenclature defines a paste as "a semisolid preparation with a stiff consistency containing a relatively high concentration of solids."

D. Gel

1. Many, but not all, gels fit within the general definition of an ointment; some would be considered thick suspensions rather than semisolids, and some are for oral rather than topical administration.

and are defined there as "semisolid systems consisting of either suspensions made up of small inorganic particles or large organic molecules interpenetrated by liquid." The proposed definition is quite similar: "a dispersion of small inorganic particles or a solution of large organic molecules rendered jellylike in consistency."

2. The gels that are thick suspensions of small inorganic particles are systems such as Aluminum Hydroxide Gel USP. Some are called magmas if the size of the dispersed phase is large (e.g., Bentonite Magma) (1). These gels must be labeled "Shake before use." Some are thixotropic, forming semisolids on standing but becoming a liquid when shaken.

3. The gels that have a more jelly-like consistency have large organic polymer molecules like carbomer, methylcellulose, and poloxamer dispersed in a liquid, usually water or a hydroalcoholic solution. An example of this type of gel is Hydrocortisone Gel USP, which is hydrocortisone

in a hydroalcoholic gel base.

E. Emollient: An agent that softens the skin or soothes irritation in skin or mucous membrane.

F. Protective: A substance that protects injured or exposed skin surfaces from harmful or annoying stimuli.

G. Occlusive: A substance that promotes retention of water in the skin by forming a hydrophobic barrier that prevents evaporation of moisture from within the skin. H. Humectant: A substance that causes water to be retained because of its hygroscopic properties.

DESIRABLE PROPERTIES OF OINTMENT BASES

Certain properties are desired for all ointment bases, no matter what their particular use. These include the following:

- A. Chemically and physically stable under normal conditions of use and storage
- B. Nonreactive and compatible with a wide variety of drugs and auxiliary agents
- C. Free from objectionable odor
- D. Nontoxic, nonsensitizing, and nonirritating
- E. Aesthetically appealing, easy to apply, and nongreasy
- **F** Remains in contact with the skin until removal is desired, then is removed easily.

CLASSIFICATION AND CHARACTERISTICS OF OINTMENT BASES

A. Many factors determine the choice of an ointment base. These include the action desired, the nature of the medication to be incorporated and its bioavailability and stability, and the desired shelf life of the finished product. The choice of a particular base matches these factors with the properties of an ointment base class.

B. Ointment Bases

The USP recognizes four general classes of ointment bases to be used therapeutically or as vehicles for active ingredients:

1. Hydrocarbon or oleaginous bases

Advantages

- (1) Inexpensive
- (2) Nonreactive
- (3) Nonirritating
- (4) Good emollient, protective, and occlusive properties

(5) Not water-washable so they stay on the skin and keep incorporated medications in contact with the skin.

c. Disadvantages

(1) These bases have poor patient acceptance because of their greasy nature.

(2) They are not removed easily with washing when this is desired (Note: may be removed

using mineral oil, which is then washed off with soap and warm water).

(3) They cannot absorb water and can absorb only limited amounts of alcoholic solutions, so most liquid ingredients are difficult to incorporate into hydrocarbon bases.

(4) Because these bases do not absorb or mix with aqueous solutions, aqueous skin secretions do not readily dissipate.

2. Absorption bases

Absorption bases have two subgroups:

(1) Anhydrous absorption bases

These are hydrocarbon bases that contain an emulsifier or emulsifiers that form water-in-oil emulsions when water or an aqueous solution is added.

(2) Water-in-oil emulsions

These are absorption bases that contain water, the amount depending on the base. As semisolid emulsions.

c. Advantages

(1) Absorption bases have moderately good protective, occlusive, and emollient properties.

(2) They do not wash off easily so they hold incorporated medications in contact with the skin.

(3) They can absorb liquids.

(a) Anhydrous absorption bases can absorb significant amounts of water and moderate amounts of alcoholic solutions.

(b) Because they already contain water, emulsion absorption bases absorb variable amounts of water and/or alcohol.

(4) Some lanolin-types have compositions somewhat like the sebaceous secretions of the skin. These are thought to have superior emollient properties.

d. Disadvantages

(1) Some bases in this group have poor patient acceptance.

(a) The anhydrous absorption bases have a greasy nature similar to that of hydrocarbon bases.

(b) Some lanolin-type bases are somewhat sticky and have a mildly unpleasant odor.

(2) They are not easily removed with washing.

(Note: As with hydrocarbon bases, they may be removed using mineral oil)

(3) Those bases containing wool wax or wool-wax alcohols may be sensitizing. Efforts have been made to remove offending principles, including detergents and natural free fatty alcohols, which is reported to reduce the incidence of hypersensitivity to almost zero.

(4) Those bases with soap-type emulsifiers (e.g., Cold Cream, Rose Water Ointment) can have the compatibility problems associated with this type of emulsifying agent.

(5) Those that contain water may have chemical stability problems with ingredients that are sensitive to hydrolysis.

(6) Those containing water are also subject to microbial growth, and the USP requires that these contain a preservative.

3. Water-removable bases

a. formulas.

b. These are oil-in-water emulsions and are classified as creams under both traditional and the proposed nomenclature schemes.

c. Advantages

(1) Water-removable bases are nongreasy and therefore aesthetically pleasing.

(2) They can be removed from the skin by washing.

(3) They can absorb some water or alcohol. If the amount of liquid added reaches a critical amount, the base will thin out to a lotion.

(4) They will allow the dissipation of fluids from injured skin.

d. Disadvantages

(1) These bases are less protective, less emollient, and less occlusive than hydrocarbon or absorption bases.

(2) Those with soap-type emulsifiers can have compatibility problems.

(3) Because these bases contain water, there may be chemical stability problems with ingredients that are sensitive to hydrolysis.

(4) The water phase is also subject to microbial growth, and the USP requires that preparations of this type contain a preservative.

(5) Because water is the external phase, these bases may "dry out" due to evaporation of the water. This can be minimized by storage in tight containers. Humectants may be added to retard dehydration; glycerin and propylene glycol in concentrations of 2% to 5% are commonly used for this purpose.

4. Water-soluble bases

b. These are greaseless ointment bases that are water-soluble. Most are polyethylene glycol-type ointment bases, and Polyethylene Glycol Ointment NF is an official preparation in this class.

c. Advantages

(1) Water-soluble bases are soluble in water and so are easily removed by washing.

(2) They leave no oil residue.

(3) They can absorb some water or alcohol; as the amount of liquid added increases, the base begins to thin out and eventually dissolves.

Pastes

1. Fatty pastes

a. Fatty pastes have properties similar to those of ointments, but they are usually thicker and seem less greasy and more absorptive than ointments. This is because they contain high concentrations of solid ingredients that absorb water and aqueous solutions.

b. Because they are better at absorbing skin secretions, they are useful when treating lesions that are weeping or oozing. They are less penetrating and stay in place on the skin better

than ointments.

c. Zinc Oxide Paste USP is an official product of this type.

2. Single-phase aqueous gel: An example of this type of paste is

Carboxymethylcellulose Sodium Paste USP, which contains 16% to 17% Sodium Carboxymethylcellulose.

3. For animal patients, pastes are an oral rather than a topical dosage form and are described as

concentrated, viscous oral dosage forms usually delivered by syringes and not intended for topical application.

Gels

Gels may be used topically, may be introduced into body cavities (nasal, vaginal, etc.), or may be used internally (e.g., Aluminum Hydroxide Gel).

1. Single-phase systems

a. The single-phase systems contain soluble macromolecules, which are linear or branched-chain polymers, dissolved molecularly in water. They are classified as colloidal dispersions because the individual molecules are in the colloidal particle size range, exceeding 50 to 100 Å.

b. The polymers are classified into one of three groups: natural polymers (e.g., tragacanth), semisynthetic cellulose derivatives (e.g., methylcellulose), and synthetic polymers (e.g., carbomer).

c. The continuous phase for these gels is usually aqueous, but alcohols, polyols, and oils may also be used.

2. Two-phase systems

a. The two-phase systems consist of a concentrated network of particulate association colloids. These are water-insoluble particles that hydrate strongly. Examples include the official preparations Aluminum Hydroxide Gel and Bentonite Magma.

b. These are thixotropic suspensions that are semisolids on standing but become fluid when agitated. The term gel is used when the dispersed particles are very small, and the term magma is used for gels with larger-sized particles.

c. Several compounds that form association colloidal gels, including bentonite, microcrys-talline cellulose, and colloidal silicon dioxide.

INGREDIENTS FOR OINTMENT BASES

1. Petrolatum USP and White Petrolatum USP

a. Description

(1) Petrolatum and white petrolatum are mixtures of purified semisolid saturated hydrocarbons extracted from petroleum. White petrolatum has undergone additional treatment, so that it is nearly decolorized, and it is preferred for pharmaceutical preparations because it is reported to cause fewer hypersensitivity receptions. The USP monographs for both compounds state that

hypersensitivity reactions. The USP monographs for both compounds state that they may contain suitable stabilizers.

(2) Petrolatum is a yellowish, translucent, soft unctuous mass. White petrolatum is similar, but as its name indicates, it is white in color. Both are tasteless, odorless, and greasy to touch. They have a melting point range of 38 to 60 degrees, and the specific gravity of the melt is 0.815 to 0.880.

b. Solubility: Petrolatum and white petrolatum are practically insoluble in water, hot or cold alcohol, acetone, and glycerin; they are soluble in most volatile and fixed oils.

c. Incompatibilities: The petrolatum bases are quite stable, and there are few problems with incompatibilities. Because the purified forms are more labile to oxidation, the USP allows addition of small amounts of antioxidants. Petrolatum does not mix with aqueous or hydroalcoholic solutions.

d. Uses

(1) White petrolatum is an, all-purpose, soft ointment base. It has a smooth texture, incorporates powders easily and spreads evenly on the skin. It is used both by itself and as a major component of combination ointment bases.

(2) If a stiffer base is desired, a portion of White Wax may be added.

e. Other names

(1) Petroleum: mineral jelly, petroleum jelly

(2) White petrolatum: white mineral jelly, white petroleum jelly, white soft paraffin, Vaseline

2. Lanolin USP and Modified Lanolin USP

a. Description

(1) Lanolin and modified lanolin are the purified, fatty, wax-like substances obtained from the wool of sheep. These substances are purified, cleaned, decolorized, and deodorized. Modified lanolin has undergone additional treatment to reduce the contents of free lanolin alcohols and detergent and pesticide residues. This modified product is intended to reduce hypersensitivity reactions. The USP monographs for both compounds state that they contain not more than 0.25% water and they may contain not more than 0.02% of a suitable antioxidant.

(2) Lanolin is a yellow, tenacious, unctuous mass with a slight characteristic odor. It melts at between 38 degrees and 44 degrees to give a clear or nearly clear yellow liquid. At 15 degrees it has a specific gravity of 0.932 to 0.945.

(3) There is often confusion between Lanolin and hydrous lanolin. Hydrous lanolin also known as Hydrous Wool Fat contains 25% to 30% water. It is a yellowish white ointment with a mild characteristic odor. Prior to USP 23, hydrous lanolin was officially known as

Lanolin, and the product now known as Lanolin was officially known as Anhydrous Lanolin. With USP 23, hydrous lanolin was deleted from the USP and the monograph for Anhydrous Lanolin was renamed Lanolin. You will still find references that use the older nomenclature.

b. Solubility: Lanolin is practically insoluble in water but will take up twice its weight of water without separation. It is sparingly soluble in cold alcohol but more soluble in boiling alcohol.

c. Incompatibilities: Lanolin is a natural product that may contain components that can act as oxidizing agents to sensitive ingredients.

d. Uses

(1) Lanolin may be used by itself, but it will also mix with vegetable oils or petrolatum to give an emollient base that is reported to penetrate the skin and give improved absorption of active ingredients.

(2) As stated earlier, it will take up to twice its weight of water to form a water-in-oil emulsion.

e. Other names: wool fat, anhydrous lanolin, refined wool fat

3. Paraffin NF

Ointment Bases

(1) Paraffin is a purified mixture of solid hydrocarbons from petroleum.

(2) It is a colorless or white translucent solid, is tasteless and odorless, and is slightly greasy to the touch. It has a congealing range of 47 to 65 degrees depending on the grade and the specific gravity of the melt is in the range of 0.84 to 0.89.

b. Solubility: Paraffin is practically insoluble in water, alcohol, and acetone but freely soluble in volatile oils and most warm fixed oils.

c. Incompatibilities: Paraffin is a stable, nonreactive compound.

d. Uses: Paraffin is used as a stiffening ingredient in ointment bases.

e. Other names: paraffin wax, hard paraffin, mineral wax

4. White Wax

a. Description

(1) White wax is the bleached, purified wax of honeybees. It consists mainly of esters of long-chain hydrocarbons, with myricyl palmitate the principle ester. It also contains free fatty acids and carbohydrates with a small amount of free wax alcohols.

(2) It is a yellowish white translucent solid, nearly tasteless but having a faint odor. The melting point is 62 to 65 degrees; the specific gravity of the melted wax is approximately 0.95.

b. Solubility: White wax is insoluble in water and sparingly soluble in alcohol. It is soluble in fixed and volatile oils.

c. Incompatibilities: White wax is a fairly unreactive compound. The free fatty acids portion can react with bases such as sodium hydroxide to form soaps. This can be used to advantage in making an emulsion-type ointment base.

d. Uses: White wax is used as a stiffening ingredient in ointment bases.

e. Other names: bleached wax, white beeswax

5. Cetyl Esters Wax

a. Description

(1) Cetyl esters wax is a mixture primarily of esters of saturated fatty alcohols and fatty acids. Cetyl esters wax is a synthetic substitute for the natural product spermaceti, which was formerly extracted from the head of sperm whales.

(2) It is white to off-white translucent flakes with a faint odor and bland, mild flavor. Its

melting point is 43 degrees to 47 degrees. When melted at 50 degrees, the specific gravity is 0.82 to

0.84.

b. Solubility: Cetyl esters wax is insoluble in water, practically insoluble in cold alcohol, but soluble in boiling alcohol. It is soluble also in volatile and fixed oils. Its solubility in mineral oil is 14 to 22 mg/mL.

c. Incompatibilities: Cetyl esters wax is quite stable and nonreactive, but it is incompatible with strong acids or bases.

d. Uses: Cetyl esters wax is a stiffening ingredient and emollient in ointment bases.

e. Other names: synthetic spermaceti.

6. Cetyl Alcohol NF

a. Description

(1) Cetyl alcohol is at least 90% cetyl alcohol with the remainder related alcohols, chiefly stearyl alcohol.

(2) It is white, waxy flakes or granules with a faint odor and a bland, mild flavour. Its melting point is 45 degrees to 50 degrees, the specific gravity of the melt being 0.908.

b. Solubility: Cetyl alcohol is insoluble in water but soluble in alcohol and in vegetable oils. When melted, it is miscible with fats, mineral oils, and paraffins.

c. Incompatibilities: Cetyl alcohol is quite stable and nonreactive, but it is incompatible with strong oxidizing agents.

d. Uses:

(1) Cetyl alcohol is used as a stiffening ingredient and emollient not only in ointment bases

but also in liquid emulsions and lotions, suppositories, and controlledrelease solid

dosage forms.

(2) It is widely used in manufactured topical products because of its favorable properties for such formulations: emollient, water absorptive, and emulsifying. It also gives these dosage forms a fine texture and good consistency.

(3) When applied to the skin, it is absorbed and retained in the epidermis. This accounts for its emollient, lubricating property. It leaves the skin feeling soft and smooth.

(4) When added to oleaginous bases such as petrolatum, it increases their ability to absorb water. In fact, when 5% is added to petrolatum, the combination will absorb 40% to 50% of its weight in water.

(5) It is used as an auxiliary emulsifier for both water-in-oil and oil-in-water emulsions. It is frequently used with detergent surfactants such as sodium lauryl sulfate to form improved barriers to coalescence in emulsion systems.

7. Stearyl Alcohol NF

a. Description

(1) Content: Stearyl Alcohol NF is at least 90% stearyl alcohol,

 $CH_3(CH_2)_{16}CH_2OH$, the remainder being related alcohols, chiefly cetyl alcohol.

(2) It is hard, white, waxy flakes or granules with a faint odor and bland, mild flavor. Its melting point is 55 degrees to 60 degrees, and the specific gravity of the melt is 0.88 to 0.91.

b. Solubility: Stearyl alcohol is insoluble in water but soluble in alcohol, propylene glycol, and vegetable oils.

c. Incompatibilities: Stearyl alcohol is quite stable and nonreactive, but it is incompatible with strong oxidizing agents.

d. Uses:

(1) Stearyl alcohol is used mainly as a stiffening ingredient, but it does have some emollient, water-absorptive, and emulsifying properties. It is used in ointment bases, liquid emulsions and lotions, suppositories, and controlled-release solid dosage forms.

(2) As with cetyl alcohol, when added to oleaginous bases such as petrolatum, it increases their ability to absorb water.

(3) In a concentration of 6% to 25%, it is used in Polyethylene Glycol Ointment NF to increase the water-absorbing ability of that water-soluble base.

8. Lanolin Alcohols NF

a. Description

(1) Lanolin alcohol is a mixture of aliphatic alcohols, triterpenoid alcohols, and sterols that are obtained by the hydrolysis of lanolin. It contains not less than 30% of sterol, calculated as cholesterol. It may contain an antioxidant.

(2) It is a hard, waxy, amber solid with a characteristic odor. Its melting point is not below 56° C.

(3) This product is a purified version of wool alcohols, which consist of a separated fraction containing cholesterol and other alcohols prepared by the saponification of grease from the wool of sheep.

b. Solubility: Lanolin alcohol is insoluble in water, slightly soluble in alcohol, and soluble 1 part in 25 parts of boiling alcohol.

c. Incompatibilities: Lanolin alcohol is incompatible with coal tar, ichthammol, phenol, and resorcinol.

d. Uses:

(1) Lanolin alcohol is used mainly as an auxiliary emulsifying agent in ointments and other topical preparations, but it does have some emollient and waterabsorptive properties.

(2) As with cetyl and stearyl alcohol, when lanolin alcohol is added to oleaginous bases such as petrolatum, it increases their ability to absorb water; 5% lanolin alcohol added to petrolatum increases threefold its ability to absorb water.

e. Other names: wool alcohols, wool-wax alcohol

9. Cholesterol NF

a. Description: Cholesterol is white to light yellow leaflets, needles, powder, or granules. It is almost odorless, has a melting point of 147 to 150 degrees, and is affected by light.

b. Solubility: Cholesterol is insoluble in water, sparingly soluble in alcohol (1g/100 mL) and dehydrated alcohol (slowly,1g/50 mL), and soluble in acetone,hot alcohol, and vegetable oils.

c. Incompatibilities: Cholesterol is a stable and nonreactive compound.

d. Uses:

(1) Cholesterol is used as an emulsifying agent in ointments and other topical preparations in concentrations of 0.3% to 5%.

(2) It also has emollient and water-absorptive properties.

10. Glyceryl Monostearate NF

a. Description

(1) Glyceryl monostearate is a mixture primarily of the monoesters of glycerin with stearic acid and palmitic acid. It may contain an antioxidant.

(2) It is a whitish, waxlike solid with a slight agreeable fatty odor and taste. It does not melt below 55 degrees, and the specific gravity of the melt is 0.92. Glyceryl monostearate is affected by light.

b. Solubility: Glyceryl monostearate is insoluble in water but soluble in hot alcohol, acetone, mineral or fixed oils.

c. Incompatibilities: The grades of glyceryl monostearate that are self-emulsifying (e.g.,Arlacel 165, Hodag CMS-D) are incompatible with acidic compounds. d. Uses:

(1) Glyceryl monostearate is used as a nonionic emulsifier for both oil-in-water and water-in-oil emulsions, both liquids and semisolids. It also has emollient properties and imparts texture and viscosity to topical preparations of various types.

(2) It is also used in solid dosage forms for multiple purposes, including as a lubricant in tablet and capsule making and as a release modifier for controlled-release oral dosage forms, suppositories, and implants. Self-emulsifying glyceryl monostearate is an ingredient in the commercial fatty acid suppository base Fattibase.

(3) Although glyceryl monostearate is the most commonly used ingredient of this type, there are numerous other glyceryl fatty acid esters such as glyceryl monooleate.

11. Stearic Acid NF

a. Description:

(1) Stearic Acid NF is a mixture primarily of stearic acid and palmitic acid. The content of stearic acid is not less than 40%, and the content of the both stearic and palmitic acids is not less than 90%. The NF also has a monograph article Purified Stearic Acid in which the stearic acid content is not less than 90% and the combined acids is not less than 96% of the total.

(2) Stearic acid is a hard, white to faintly yellowish, glossy, crystalline solid or powder with a slight odor and taste of tallow; it melts at approximately 55 degrees, with the purified acid melting at 69 to 70 degrees.

(3) Both Stearic Acid and Purified Stearic Acid must be labeled for external use only, unless they are made entirely from edible sources.

b. Solubility: Stearic acid is practically insoluble in water. It is soluble as 1 g/20 mL alcohol or 25 mL acetone and in propylene glycol.

c. Incompatibilities

(1) As discussed in d(2), stearic acid reacts with alkali and organic bases to form stearate soaps. In most cases, this is an intended reaction, as with nascent soap emulsifying agents and with the in situ formation of sodium stearate in Glycerin Suppositories USP.

(2) It also reacts with metal hydroxides to form water-insoluble stearates, and salts of zinc and calcium are reported to react with stearic acid in ointment bases to give lumpy preparations.

d. Uses

(1) Stearic acid is widely used as an emulsifying and solubilizing agent in topical preparations. It is also used as a lubricant in tablet and capsule making.

(2) Stearic acid is the fatty acid part of a soap emulsifier used for waterremovable o/wemulsion bases. The base part may be sodium or potassium hydroxide, sodium carbonate or triethanolamine. When excess stearic acid is added, the unneutralized stearic acid is emulsified as part of the oil phase. This free stearic acid gives these creams a pearlescent luster; they are known as vanishing creams. Because of the inherent compatibility problems of soap emulsifiers, some newer vanishing cream formulations use nonionic surfactants, but stearic acid is still added for the desirable pearl luster.

12. Polyethylene Glycol NF (PEG)

a. Description

Polyethylene glycols are available as various grades from 200 to 8,000, where the assigned number indicates the average molecular weight. Those with numbers 200 through 600 are clear, viscous liquids, PEG 900 and 1,000 are soft solids, and PEGs 1,450 to 8,000 are white, waxy solids or flakes. All are odorless and tasteless, and the pH of a 5% solution is in the range of 4.5 to 7.5. Solubility: Although all PEGs are soluble in water and in many organic solvents, their solubilities depend on their molecular weight. The liquid PEGs are soluble in acetone, alcohol, glycerin, and glycols; solid PEGs are soluble in acetone and alcohol and slightly soluble in aliphatic hydrocarbons but are insoluble in fats, fixed oils, and mineral oil.

Incompatibilities:

(1) Although these compounds are quite stable, polyethylene glycols may cause problems for compounds subject to oxidation because of the presence of residual peroxide impurities from the manufacturing process.

(2) Other reported incompatibilities include reduced antibacterial activity of some antibiotics, including penicillin and bacitracin; reduced preservative effectiveness of the parabens owing to binding with PEG; liquification of PEG bases with phenol, tannic acid, and salicylic acid (although the original USP formula for benzoic and salicylic acid ointment, also known as Whitfield's Ointment, used PEG Ointment as the base); discoloration of sulfanilamides; precipitation of sorbitol; and softening or other reactions with some plastics and some membrane filters.

Uses:

(1) Polyethylene glycols are widely used in pharmaceutical products and preparations. They are used as ointment and suppository bases, solvents, viscosity-increasing agents, plasticizers, and lubricants in tablet and capsule making. They are approved for use in oral, topical, rectal, ophthalmic, and parenteral products.
(2) Their usefulness is limited by the fact that they may be irritating to delicate tissues, mucous membranes, and denuded skin. Although their water-solubility would seem to make them good vehicles to use on burned or denuded skin, they must be used with caution in these situations, both because of their irritating nature and because there have been reports of systemic toxicity due to absorption from these areas. There have also been reports of hypersensitivity reactions.

(3) The limitation for parenteral products is 30% v/v of PEG 300.e. Other names: PEG, Carbowax, Atpeg, Hodag PEG.