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A REVIEW Ointments; Concepts, Types, Bases, Manufacturing and Therapeutic Applications

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Abstract

Ointments are semisolid preparations intended primarily for application to the skin or to certain mucous membranes. They consist of one or more active pharmaceutical ingredients incorporated into a suitable base that may be oleaginous, absorption, water-removable, or water-soluble in character. The performance of an ointment depends not only on the identity and concentration of the drug, but also on the physicochemical properties of the base, particle size of incorporated solids, method of manufacture, degree of homogeneity, viscosity, spread ability, drug release, stability, packaging, and storage. This review describes the formulation principles, classification, selection of ingredients, preformulating considerations, and major methods used in ointment manufacture, with particular emphasis on incorporation, levigating, trituration, and fusion. The preparation sequence is aligned with the supplied reference material, including size reduction, levigating, mixing with the base, trituration, homogenization, filling, packaging, labeling, and storage. The review also discusses critical quality attributes and evaluation tests such as appearance, homogeneity, grittiness, pH where applicable, viscosity/Rheology, spread ability, extrudability, drug content, in-vitro drug release, microbial quality, and stability. Special attention is given to packaging compatibility, patient information, and common manufacturing defects. The objective is to present a coherent, textbook-based account that can serve as a B.Pharm. academic reference for understanding how a well-designed ointment is prepared, evaluated, packaged, and maintained throughout its intended shelf life.

Keywords: Ointment formulation; Semisolid dosage forms; Ointment bases; Manufacturing methods; Quality evaluation

1.Introduction;

Ointments occupy an important position among topical semisolid dosage forms because they can protect the skin, deliver drugs locally, and, depending on the formulation, provide an occlusive environment that can reduce trans epidermal water loss. Their formulation is apparently simple, yet achieving a stable and elegant product requires careful control of the base, drug particle size, temperature, mixing sequence, and final consistency. Standard pharmaceuticals texts describe ointments as preparations in which medicament are

dissolved, suspended, or otherwise dispersed in an appropriate semisolid vehicle. The vehicle is therefore not an inert background; it strongly influences drug release, skin interaction, Washability, stability, and patient acceptability.

From a manufacturing perspective, an ointment should be viewed as a structured dispersion or solution whose physical properties are determined by the interactions among the drug, excipients, and manufacturing conditions. A drug may be incorporated by dissolving it in a suitable phase, dispersing it as a fine powder, or adding it to a previously prepared base. When solids are present, reduction of particle size and levigating can reduce grittiness and improve uniformity. When the formulation contains Ingredients with different melting points, fusion is performed in a controlled order so that the components are melted without unnecessary exposure to heat.

The supplied reference material presents the practical sequence as a series of connected steps: preformulating and ingredient selection, accurate weighing, base preparation, drug incorporation or fusion, cooling and filling, packaging/labeling and storage, followed by evaluation. It also emphasizes size reduction, levigating, mixing with the base, trituration, homogenization, and filling as key process operations. These steps are consistent with the general principles described in standard pharmaceuticals texts and are developed in greater detail in the sections below.

2.Objectives of Ointment Formulation:

The formulation of an ointment is undertaken to achieve a product that delivers the intended therapeutic effect while remaining physically, chemically, microbiologically, and cosmetically acceptable throughout its shelf life. The major objectives include:

- ❖ To deliver an active pharmaceutical ingredient to the intended site of application at an appropriate rate and concentration.
- ❖ To produce a smooth, homogeneous preparation that is free from objectionable grittiness and visible phase separation.
- ❖ To obtain suitable consistency, spread ability, adhesiveness, and washability for the intended route and site of administration.
- ❖ To protect the drug from environmental factors such as moisture, oxygen, and light when required.
- ❖ To maintain acceptable drug content and uniformity during manufacturing, filling, storage, and use.
- ❖ To provide adequate physical and chemical stability and appropriate microbiological quality.
- ❖ To select packaging and labelling that preserve product quality and provide clear directions for safe use

3.Classification of Ointments and Ointment Bases;

Ointments may be classified according to their therapeutic use, site of application, composition, or nature of the base. The supplied reference material illustrates a practical classification into medicated and unmedicated ointments, with medicated ointments further associated with applications such as ophthalmic, dermatological, rectal, vaginal, and nasal preparations. Such classifications are useful because the intended site imposes specific requirements for sterility, irritation potential, particle size, base composition, and packaging.

Table.1:

Category	General characteristics	Typical considerations
Medicated ointments	Contain one or more active pharmaceutical ingredients.	Drug stability, dose uniformity, release, skin compatibility.
Unmedicated ointments	Contain no therapeutic active ingredient and may be used as protective or bases.	Emollient, occlusive, texture, compatibility.
Oleaginous bases	Hydrocarbon-rich and highly occlusive; generally, not readily washable with water.	Excellent emollient; prolonged contact; limited washability.
Absorption bases	Can incorporate aqueous solutions and may form water-in-oil systems.	Useful when aqueous ingredients must be incorporated into an oleaginous vehicle.
Water-removable bases	Oil-in-water emulsion type systems, often washable with water.	Improved Washability and cosmetic acceptability.
Water-soluble bases	Prepared from water-soluble materials and contain no oleaginous phase.	Non-greasy; readily washable; may be less occlusive.

The four classical base groups are particularly important in pharmaceuticals: oleaginous, absorption, water-removable, and water-soluble bases. Selection depends on the desired therapeutic effect and the physicochemical properties of the drug. An oleaginous base may be selected when occlusion and emollient are desirable, whereas a water-removable base may be preferred when a less greasy and more washable product is required. Water-soluble bases can be useful where a non-greasy preparation is desired, but their behavior in the presence of water and their potential for drying effects should be considered.

5. Formulation Components;

5.1 Active Pharmaceutical Ingredient

The drug substance should be evaluated for solubility, particle size, polymorphic form, melting point, chemical stability, pKa, partitioning behavior, and compatibility with the selected base. Drugs intended for topical action may need to remain at the skin surface or penetrate into the stratum corneum. The formulation should therefore balance retention in the vehicle with adequate release from the base. For suspended drugs, fine and appropriately controlled particle size is particularly important because coarse particles may produce a gritty product and may also compromise uniformity.

5.2 Ointment Base

The base provides the vehicle in which the drug is dissolved or dispersed. Its polarity, viscosity, melting behavior, water content, emulsification properties, and interaction with skin influence the final product. Base selection should also consider the desired release profile and whether the product is intended for normal skin, damaged skin, mucosal surfaces, or specialized sites.

5.3 Antioxidants and Preservatives

Some formulations require antioxidants to reduce oxidative degradation of susceptible drugs or excipients. Preservatives may be required particularly when the preparation contains water and is susceptible to microbial growth. The choice and concentration must be justified by compatibility, efficacy, route of administration, regulatory requirements, and the intended packaging system. An anhydrous hydrocarbon ointment has a different preservation requirement from a water-containing emulsion-type semisolid.

5.4 Other Excipients

Other formulation aids may include humectant, surfactant, stiffening agents, emollients, penetration modifiers, chelating agents, and pH-adjusting agents. Each excipient should perform a defined function and should not adversely affect drug stability, release, skin tolerance, or product appearance.

6. Preformulation Considerations

Preformulation provides the scientific basis for choosing a suitable base and manufacturing method. For ointments, the most important questions concern the drug's solubility in the vehicle, thermal behavior, particle size, moisture sensitivity, chemical stability, and potential interactions with excipients. The intended therapeutic site must also be considered. For example, preparations for ophthalmic use require much stricter control of sterility and particulate matter than ordinary dermatological ointments.

Table.2:

Parameter	Why it matters in ointment development	Typical approach
Solubility in base	Determines whether the drug is dissolved or dispersed and influences release.	Solubility screening in candidate bases/phases.
Particle size	Affects grittiness, uniformity and dissolution/release of suspended drug.	Sieving, milling, microscopic assessment.
Melting point	Determines fusion sequence and processing temperature.	Reference data and thermal analysis when needed.
Drug-excipient compatibility	Prevents degradation or undesirable physical changes.	Stress studies, spectroscopy/thermal methods.
Moisture sensitivity	Can alter consistency, stability and microbial risk.	Water activity/moisture assessment where relevant.
Rheology	Controls spreadability, filling behavior and patient use.	Viscosity/rheological profiling.
Skin compatibility	Reduces risk of irritation or sensitization.	Literature review and appropriate safety evaluation.

7. Preparation of Ointments;

The manufacturing method is selected according to the physical state and properties of the ingredients. The two classical approaches are incorporation and fusion. Incorporation is generally used when the ingredients can be mixed without melting the base, whereas fusion is preferred when one or more base ingredients must be melted to obtain a uniform product. In practice, the methods may overlap: a fused base can be prepared first and a heat-sensitive drug can subsequently be incorporated during cooling.

General Manufacturing Flow



7.1 Incorporation Method

Incorporation involves mixing the active ingredient and other components into an ointment base without necessarily melting the entire formulation. It is particularly suitable when the drug is stable at room temperature and can be adequately dispersed in the base. A solid drug is first reduced to a fine powder, passed through a suitable sieve when appropriate, and then levigated with a small amount of a compatible liquid or a portion of the base. The resulting smooth concentrate is incorporated gradually into the remaining base by geometric dilution or systematic mixing. The process is continued until a uniform preparation is obtained.

1. Accurately weigh the active ingredient and all excipients.
2. Reduce the particle size of solid drug material when required and remove large particles by appropriate screening.
3. Levigate the powder with a small quantity of a suitable levigating agent to form a smooth paste.
4. Add a small portion of the ointment base to the paste and mix thoroughly.
5. Continue addition of the base in portions, using geometric dilution to promote uniform distribution.
6. Triturate or mix until the preparation becomes smooth and homogeneous.
7. Adjust the final weight and homogenize when required.
8. Fill into the selected container and complete labeling and storage requirement.

7.2 Levigation

Levigation is a size-reduction and wetting operation used to produce a smooth dispersion of an insoluble powder. The solid is triturated with a small amount of a suitable levigating agent that is compatible with the drug and base. The liquid reduces interparticle friction and helps wet the powder. Commonly used levigating agents include mineral oil for oleaginous systems and glycerin or propylene glycol for some hydrophilic systems, but the choice must be formulation-specific. Levigation is not simply dilution; it is primarily intended to improve particle dispersion and reduce grittiness.

7.3 Trituration and Geometric Dilution

Trituration may be performed in a mortar using appropriate pressure and circular movement to reduce particle size and distribute the material uniformly. When a small quantity of drug is being mixed with a much larger quantity of base, geometric dilution helps prevent localized high concentrations. Approximately equal portions are mixed successively so that the concentration difference between the mixture and the remaining base is progressively reduced. This is especially useful in extemporaneous compounding and in small-scale formulation work.

7.4 Fusion Method

Fusion is selected when the ointment contains solid ingredients that require melting or when a base must be formed by combining components in the molten state. The supplied reference material specifically indicates that, when solid ingredients have different melting points, they may be melted in descending order of their melting points. This principle minimizes unnecessary heating of lower-melting ingredients and helps produce a uniform base. After melting, the components are mixed, the drug is incorporated by an appropriate method, and the product is cooled under controlled conditions.

1. Select and accurately weigh all ingredients according to the formula.
2. Identify the melting points and heat sensitivities of the solid components.
3. Melt the components in a suitable vessel, normally beginning with the highest-melting materials and adding lower-melting materials as appropriate.
4. Maintain sufficient mixing to obtain a clear or uniform molten phase without excessive heating.
5. Remove from heat and incorporate the drug by dissolution or dispersion, depending on its properties.
6. Continue mixing during cooling to reduce the risk of settling, crystallization, or phase separation.
7. Homogenize the semisolid when required to achieve uniform texture.
8. Fill into suitable containers while the product has adequate flow for accurate filling, avoiding conditions that introduce air or contamination.



7.5 Cooling and Homogenization

Cooling is a critical process stage because the micro structure of an ointment can develop during solidification. Rapid or uncontrolled cooling may lead to undesirable crystal forms, graininess, contraction, or separation in some formulations. Controlled agitation during cooling can improve uniformity and texture. Homogenization may be used when the formulation contains dispersed phases or when a more uniform particle distribution is needed. The extent of homogenization should be optimized because excessive shear can alter structure and may increase air incorporation.

8. Critical Process Variables:

Table.3:

Process variable	Potential impact if poorly controlled	Control strategy
Temperature	Degradation, evaporation, altered base structure.	Use validated/controlled temperature ranges and minimize unnecessary heating.
Order of addition	Incomplete melting, poor dispersion or instability.	Follow a defined manufacturing sequence based on melting and compatibility
Mixing intensity	Non-uniformity or excessive air incorporation.	Use appropriate mixing speed and time.
Particle size	Grittiness and poor dose distribution.	Size reduction and controlled screening/levigation.
Cooling rate	Crystal growth, graininess, phase separation.	Controlled cooling with appropriate agitation.
Fill temperature	Poor filling, contraction or container deformation.	Select a suitable filling temperature based on product behavior.

9. Evaluation of Ointments;

Evaluation determines whether the finished ointment meets predefined quality requirements. Because ointments are complex semisolid systems, no single test is sufficient. A combination of physical, chemical,

performance, microbiological, and stability tests provides a more meaningful assessment. The exact specifications depend on the product, route, pharmacopeial requirements, and intended use.

9.1 Appearance and Organoleptic Properties;

The product is visually inspected for color, odor, texture, gloss, uniformity, and visible particulate matter. A well-prepared ointment should generally have an acceptable appearance consistent with its formulation. Changes such as discoloration, phase separation, oil bleeding, excessive hardness, or graininess may indicate instability or a manufacturing problem.

9.2 Homogeneity and Grittiness;

Homogeneity indicates that the active ingredient and excipients are uniformly distributed. Grittiness is particularly important for preparations containing suspended solids. The ointment may be examined by spreading a thin layer or by suitable microscopic or tactile assessment under controlled procedures. For specialized preparations such as ophthalmic products, particulate control is much more stringent.

9.3 pH

pH is most meaningful for ointments that contain an aqueous phase or can be dispersed in a suitable aqueous medium for testing. An appropriate pH can reduce irritation and support chemical stability. Because a conventional hydrocarbon ointment may not have a directly measurable aqueous pH, the test procedure should be selected according to the formulation rather than applied mechanically.

9.4 Viscosity and Rheology;

Viscosity and rheological behavior affect spreadability, extrudability, filling, residence time, and patient acceptability. Many ointments are non-Newtonian and may show plastic or pseudoplastic behavior. Temperature must be controlled during testing because semisolid viscosity is strongly temperature-dependent. A suitable rheological profile can help ensure batch-to-batch consistency.

9.5 Spreadability;

Spreadability expresses how readily a semisolid can be distributed over a surface under a defined force. It is influenced by viscosity, yield stress, particle size, and base composition. A simple academic method may use two glass plates and a known load to measure the time or distance associated with spreading. More advanced approaches use texture analyzers or rheometers.

9.6 Extrudability;

Extrudability is important for ointments packaged in collapsible tubes. It describes the ease with which the product can be expelled from the container under a specified force. It depends on viscosity, yield stress, tube dimensions, orifice size, and product structure. Excessive resistance can reduce patient convenience, while very easy extrusion may indicate inadequate structure.

9.7 Drug Content and Content Uniformity;

The active ingredient should be assayed using a validated analytical method appropriate to the drug. The test confirms that the formulation contains the intended amount of drug and, where applicable, that samples taken from different locations or containers are adequately uniform. Assay is particularly important for preparations in which the active ingredient is present at a low concentration.

9.8 In-vitro Drug Release;

In-vitro release studies help characterize the rate at which drug leaves the semisolid formulation. Depending on the formulation and study objective, diffusion cells or other validated release systems may be used with an appropriate receptor medium and membrane. The resulting release profile can be compared between formulations and during stability studies. In-vitro release does not by itself establish clinical bio availability, but it is a useful product-performance tool.

9.9 Microbial Quality;

Microbial quality is especially important for water-containing ointments and preparations intended for sensitive sites. Testing and preservative effectiveness requirements depend on the product and applicable pharmacopeial standards. Good manufacturing practice, hygienic processing, suitable water quality, and compatible packaging are fundamental controls.

10. Stability Studies;

Stability evaluation examines whether the ointment retains acceptable appearance, consistency, drug content, microbial quality, and performance under defined storage conditions. Potential changes include oxidation, hydrolysis, color change, odor development, viscosity drift, phase separation, crystallization, and drug degradation. Both physical and chemical stability should be considered.

Table.4:

Evaluation test	What it indicates	Importance
Appearance	Colour, Odor, texture, phase condition	Rapid indication of product quality and instability.
Homogeneity / grittiness	Uniformity and smoothness.	Important for dose distribution and patient acceptability.
pH (where applicable)	Acid–base environment of aqueous phase.	Supports stability and skin compatibility.
Viscosity / Rheology	Flow and structural behavior.	Predicts filling, spreadability and user experience.
Spreadability	Ease of application.	Important for topical use and patient acceptance.
Extrudability	Ease of removal from tube.	Important for packaged semisolid.
Drug content	Amount of active ingredient.	Confirms potency and batch consistency.
In-vitro release	Drug liberation from formulation.	Useful for formulation comparison and performance.
Microbial quality	Microbial burden/acceptability.	Essential for safety, especially for aqueous products.
Stability	Quality over time under storage conditions.	Supports shelf life and packaging selection.

11. Packaging, Labelling and Storage;

Packaging is an integral part of ointment quality because the container can protect the product from contamination, light, oxygen, moisture, and mechanical damage. The selected package should be compatible with the formulation and should not adsorb, absorb, react with, or otherwise alter the drug. Common containers include collapsible metal or plastic tubes and suitable jars or containers, depending on the formulation and intended use.

The supplied reference material represents packaging and labelling as a sequence beginning with selection of a compatible container, followed by filling and sealing, recording batch/date details, providing directions and warnings, adding storage statements, and supplying patient information. In a finished pharmaceutical product,

labelling should provide enough information for correct use while complying with applicable regulatory requirements.

- Use a container compatible with the ointment base and active ingredient.
- Fill and seal in a manner that minimizes contamination and excessive air entrapment.
- Include appropriate batch or lot identification and relevant date information.
- Provide directions for use and important warnings or precautions.
- State storage conditions when temperature, light, moisture, or other environmental factors are important.
- Include patient-oriented information appropriate to the product and route of administration

12.Common Defects and Their Causes;

Defect	Possible causes	Corrective/preventive approach
Grittiness	Large particles, incomplete levigation, crystallization.	Improve size reduction, Levigation and cooling control.
Phase separation	Incompatible components, inadequate emulsification, poor cooling.	Review formulation, mixing and temperature profile.
Oil bleeding	Structural instability or excessive heating.	Optimize base composition and cooling.
Excessive hardness	High proportion of stiffening solids or overcooling.	Adjust composition and process conditions.
Poor spreadability	High yield stress or excessive viscosity.	Optimize base and rheological profile.
Drug non-uniformity	Inadequate mixing or poor particle dispersion.	Use geometric dilution, adequate mixing and homogenization.
Color/odor change	Oxidation, degradation, contamination.	Use compatible antioxidants, packaging and storage controls.
Air bubbles	Excessive agitation or poor filling technique.	Optimize mixing and filling conditions.
Container interaction	Adsorption, absorption or chemical incompatibility.	Perform packaging compatibility studies.

13.Conclusion:

Ointments are versatile semisolid dosage forms whose quality depends on rational formulation, controlled preparation, appropriate evaluation, and suitable packaging. The principal preparation methods—incorporation and fusion—can be supported by size reduction, Levigation, trituration, geometric dilution, controlled cooling, and homogenization as required by the formulation. Evaluation should cover physical characteristics, Rheology, spreadability, extrudability, drug content, release, microbial quality, and stability, with test selection matched to the nature and intended use of the product. The use of a compatible container, accurate labelling, and appropriate storage conditions is equally important because product quality must be maintained throughout its shelf life. Overall, successful ointment development requires integration of pharmaceuticals principles with process control and quality assurance rather than reliance on consistency or appearance alone.

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13. Relevant current national regulatory requirements and institutional standard operating procedures should be consulted before practical compounding or clinical use.