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COLD EMULSIFICATION TECHNOLOGY IN THE PRODUCTION OF MEDICINAL OINTMENTS AND ITS ADVANTAGES

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Abstract: This article examines the cold emulsification technology applied in the manufacturing of medicinal ointments (semi-solid dosage forms). Cold emulsification is a technique in which aqueous and oily phases are combined without heating or with minimal thermal exposure. This approach ensures the stability of thermolabile active ingredients, prevents degradation of auxiliary excipients, and reduces energy consumption during production. The study analyzes the technological stages, criteria for selecting emulsifiers, phase compatibility, and the physicochemical characteristics of the final product. The results demonstrate that ointments manufactured by cold emulsification possess enhanced dispersity, uniform consistency, and increased formulation stability.

Keywords: cold emulsification, semi-solid dosage forms, medicinal ointment, emulsification, thermolabile substances, emulsifier, dispersity, stability, technological process.

Introduction

Semi-solid dosage forms, particularly medicinal ointments, are widely used in dermatology, surgery, pediatrics, and cosmetology due to their ability to deliver active pharmaceutical ingredients (APIs) through the skin for local or systemic therapeutic action. Their complex composition, rheological properties, emulsion stability, and the proper selection of stabilizing agents determine the quality and clinical performance of the formulation. Therefore, optimization of ointment manufacturing technologies remains one of the pressing areas of modern pharmaceutical science.

In traditional hot-emulsification technology, both oil and aqueous phases are heated to 60–80 °C prior to mixing. However, such thermal exposure may compromise the safety and stability of sensitive compounds. Heating can trigger oxidation of plant extracts and essential oils, degrade vitamins (A, C, E), and disrupt the structural integrity of certain polymers and organic emulsifiers.

Consequently, the final product may lose therapeutic efficacy, exhibit discoloration, off-odor, or reduced stability.

Cold emulsification technology has emerged as an effective and energy-efficient alternative capable of overcoming these limitations. In this method, emulsification is performed at approximately 20–30 °C without additional heating. Low-temperature processing preserves the biological activity of thermolabile components, facilitates the formation of uniform emulsions, and improves the structural attributes of the ointment matrix.

Cold emulsification is particularly advantageous for ointments containing:

- heat-sensitive vitamins (A, E, C),
- phytocomplexes and polyphenols,
- essential oils,
- probiotic or enzymatic complexes,
- natural antioxidants and bioflavonoids.

Furthermore, the absence of heating and cooling steps significantly reduces production costs, lowers energy consumption, minimizes mechanical stress on equipment, and decreases environmental impact. Owing to its simplicity and high efficiency, the method is suitable not only for industrial-scale manufacturing but also for small and medium-sized pharmaceutical production units.

The relevance of this study is reinforced by the increasing demand for natural, thermally stable, safe, and bioactive ointments in today's pharmaceutical market. A detailed scientific evaluation of cold-emulsification processes and their advantages provides essential insights for advancements in pharmaceutical technology.

Technological Stages of Cold Emulsification

Incorporation of the Aqueous Phase into the Oil Phase (Primary Emulsification)

The aqueous phase is added gradually in a thin stream to the oil phase.

Stirring speed is maintained between **900–1500 rpm**.

Temperature remains within **20–30 °C**.
Objective: formation of an O/W or W/O emulsion with fine, uniform droplets without thermal degradation.

Addition of Active Ingredients

Thermosensitive APIs (vitamins, essential oils, polyphenols) are incorporated after emulsification.

Homogenization ensures uniform distribution of the active substances.
Objective: preserve the biological activity of all sensitive components.

Plant-Derived Bioactive Substances Preferentially Processed by Cold Emulsification.

Cold emulsification is particularly advantageous in the formulation of ointments enriched with phytochemicals, since many botanical extracts contain thermolabile constituents that rapidly degrade when exposed to elevated temperatures. The following plant species represent key examples of botanicals whose pharmacological activity is best preserved under low-temperature processing.

1. Plants Rich in Heat-Sensitive Phytocomplexes

1.1. Aloe vera (Aloe barbadensis Miller)

Major bioactive compounds: polysaccharides (acemannan), amino acids, vitamins A, C, and E.

Rationale for cold emulsification:

Aloe polysaccharides undergo structural degradation above 45–50 °C.

Antioxidant vitamins oxidize rapidly when heated, reducing biological potency.

Pharmaceutical applications: wound-healing gels, burn ointments, anti-inflammatory dermatological formulations.

2. Plants Containing Essential Oils and Terpenoids

2.1. Lavender (Lavandula officinalis)

Active constituents: linalool, linalyl acetate.

Advantages of low-temperature processing:

Essential oils exhibit high volatility and evaporate significantly at 60 °C or higher.

Cold emulsification retains the plant's aromatherapeutic and antimicrobial characteristics.

Applications: calming creams, soothing balms, antibacterial ointments.

2.2. Tea Tree (Melaleuca alternifolia)

Main compound: terpinen-4-ol.

Importance of cold processing:

Thermal exposure diminishes its antibacterial activity.

Low-temperature emulsification maintains its broad-spectrum antimicrobial effect.

Applications: acne ointments, antiseptic creams, wound disinfecting gels.

3. Plants Rich in Flavonoids and Polyphenols

3.1. Rosehip (Rosa canina)

Contains: anthocyanins, flavonoids, high concentrations of vitamin C.

Reason for cold emulsification:

Vitamin C initiates oxidation starting at 40 °C.

Polyphenols lose antioxidant activity when heated.

Dermatological uses: antioxidant creams, skin-repair balms, rejuvenating formulations.

3.2. Ginger (Zingiber officinale)

Active compounds: gingerols and shogaols.

Thermal concern:

Gingerols convert to shogaols under heat, altering their pharmacodynamic profile.

Uses: anti-inflammatory gels, analgesic ointments for joint and muscle pain.

4. Bark- and Leaf-Derived Bioflavonoid Sources

5. 4.1. Horse Chestnut (Aesculus hippocastanum)

Key constituents: aescin and various flavonoids.

Heat sensitivity:

Aescin undergoes decomposition at 55–60 °C.

Cold processing preserves its venotonic and angioprotective properties.

Applications: anti-varicose gels, capillary-strengthening creams.

4.2. Barberry (Berberis vulgaris)

Bioactive compound: berberine (a thermolabile isoquinoline alkaloid).

Cold emulsification benefit:

Maintains berberine's antimicrobial and anti-inflammatory activities.

Used in: antiseptic ointments, anti-inflammatory dermatological preparations.

5. Plants with Strong Antioxidant Capacities

5.1. Green Tea (Camellia sinensis)

Phytochemicals: catechins, particularly epigallocatechin gallate (EGCG).

Thermal limitation:

Catechins polymerize at elevated temperatures, losing antioxidant efficacy.

Applications: anti-aging creams, UV-protective balms, antioxidant gels.

5.2. Turmeric (Curcuma longa)

Principal compound: curcumin.

Thermal degradation:

Curcumin is prone to oxidative breakdown when heated.

Cold emulsification preserves its anti-inflammatory and wound-healing properties.

Formulations: regenerative balms, anti-inflammatory ointments.

6. Enzyme- and Probiotic-Enriched Botanical Sources

These extracts contain extremely thermolabile enzymatic structures:

Saccharomyces yeast extract

Papaya extract (papain)

Pineapple extract (bromelain)

Reason for cold emulsification:

Enzymes denature at 40 °C and above, resulting in the loss of proteolytic or regenerative activity.

Use cases: keratolytic creams, exfoliating gels, dermal regeneration enhancers.

Homogenization

The emulsion is processed through a homogenizer at **3000–8000 rpm**.

Droplet size distribution is measured to ensure adequate dispersity.

Viscosity and plasticity adjustments are made if required.

Stabilizers such as carbopol or sodium alginate may be added.
Objective: obtain a smooth, stable, non-separating ointment structure.

Quality Control of the Final Product

I. Appearance (color, odor, consistency),

II. pH level (acceptable range: **5.0–7.0**),

III. Mechanical stability,

IV. Viscosity, spreadability, and uniformity.

The product is then filled into aluminum or polymer tubes, sterile syringe-tubes, or jars, and hermetically sealed.

Packaging, Labeling, and Storage

Products are labeled according to regulatory guidelines.

Stored at **15–25 °C**, protected from direct light.
Objective: maintain chemical and physical stability throughout the shelf life.

Conclusion

Cold emulsification technology provides several significant advantages over the traditional hot-emulsification process in the production of medicinal ointments.

Carrying out the process at low temperatures preserves the biological activity of heat-sensitive vitamins, essential oils, phytoextracts, enzymes, and other bioactive substances. Consequently, the final formulation demonstrates superior therapeutic efficacy, consistent color and odor, and resistance to oxidative or thermal degradation.

This method improves the stability of the dispersed system, enhances the homogeneity and smoothness of the ointment, and ensures better spreadability and dermal absorption. The elimination of heating steps reduces energy expenditure, lowers production costs, and improves ecological safety. Its simplicity and flexibility make cold emulsification a highly applicable approach even in small-scale pharmaceutic compounding settings.

Overall, the findings indicate that cold emulsification is a promising, efficient, and innovative technique in modern pharmaceutical technology, enabling the production of high-quality semi-solid dosage forms with improved safety and functionality.

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